In Contact

Spring 2014

NHS
National Institute for Health Research

Clinical Research Network
Primary Care

Primary Care Clinical Research & Trials Unit
Networks
CTU
Primary Care
PC-CRTU

Studies taking place in your area

Commercial Research Opportunities

Research Ready in Community Pharmacies

NHS National Institute for Health Research

Clinical Research Network
Primary Care

Welcome

Colleagues,

First, I want to start with a big thank you to you all for helping us to recruit 8,175 patients into research studies. This is absolutely fantastic and long may it continue!

Secondly, as you know, the NHS has been going through major changes during the past year and changes are also coming for the NIHR Clinical Research Networks (CLRN's). These are being reorganised and within the West Midlands region the 3 CLRN's will become one Local Clinical Research Network and will be hosted by the Royal Wolverhampton NHS Trust. Despite these changes, we will continue to engage and work with you as before to promote and increase the number of patients and practices in research studies across the Birmingham and Black Country area.

In addition to the current initiatives, we have pump-primed the Research Sites Initiative (RSI) to 23 general practices this year and will be extending this to more from 1 April 2014.

For further details of this scheme contact:

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We have also introduced this scheme to 50 pharmacies and again will be promoting to all our colleagues in primary care. So you can see that this has been a very research active and productive year despite the many challenges Primary Care faces.

We will of course keep you updated with further developments and look forward to another fruitful year.

Dr Paramjit Gill
Clinical Lead, CRN: Primary Care

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ROYAL PHARMACEUTICAL SOCIETY

RESEARCH READY

NHS National Institute for Health Research

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CRN: Primary Care to establish research infrastructure in community pharmacies.

The Clinical Research Network: Primary Care is increasing the capacity and capability for primary care research in Birmingham and The Black Country (BBC) by rolling out a new scheme from the Royal Pharmaceutical Society called 'Research Ready'. Developed by Pharmacy Research UK in conjunction with the Royal College of General Practitioners and the National Institute for Health Research, it is aligned with the latest Research Governance Frameworks.

This new scheme is open to all independent community pharmacies and is an online self-accreditation tool covering the basic requirements for undertaking primary care research in the UK. The first 30 community pharmacies that are successful in their 'Research Ready' accreditation will be allocated funding to cover research infrastructure costs, which includes research-related requirements such as Good Clinical Practice (GCP) training.

Dr Feltham, Research Manager for the CRN: Primary Care in the BBC, commented: 'This is a very exciting scheme as we look to expand our recruitment pathways for our studies. Patient footfall in community pharmacies is very high and increasing awareness of specific studies and clinical research in general will benefit recruitment in the trials we are supporting'.

There are a number of benefits to the pharmacy becoming 'Research Ready' accredited:

- Pursuit of an interest in a specific aspect of practice
- Greater multidisciplinary working and integration in the wider healthcare team
- Contribution to CPD
- Improve the quality of care and patient outcomes
- Evidence to support service commissioning
- Building stronger links with industry and academia

For more information about the 'Research Ready' accreditation please contact or email us on the details below.

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Commercial studies

CRN: Primary Care is looking for GP practices to participate in the increasing number of commercial research studies in our portfolio.

The CRN: Primary Care is looking to recruit new practices to take part in commercial studies by becoming a Patient Identification Centre (PIC). This initiative aims to strengthen you and your practice's participation in commercial studies, which provides your patients with access to novel treatments and interventions supported by the National Institute for Health Research (NIHR).

What is a PIC Site?

PIC sites are organisations that identify potential participants for a study taking place in another organisation. Your practice being a PIC site, allows your patients to access clinical trials taking place in other sites (ie, a local hospital or another GP practices). All studies are ethically approved and are adopted onto the NIHR Portfolio.

What is involved for the practice?

- Patients are identified by searching the GP computer system
- Patients are then mailed out from the practice and asked to contact the study team undertaking the research

Benefits of becoming a PIC site

- Patients benefit from access to new treatments, interventions and medicines
- Enhanced partnership between primary and secondary care research
- Acting as a PIC site provides an additional income stream for your practice
- Patients will be reimbursed for any costs incurred travelling to clinic appointments

Remuneration:

GP practices who act as PIC sites will be paid £250 per study to cover the following:

- Stationery and postage for patient invite letters
- Time to run the search and screen the patient list
- Providing the secondary care site with a brief medical history for any patient invited for screening and randomised (once patient consent provided)
- An additional payment to your practice of £50 for every patient randomised into a study

If you and your practice would like to apply for this new initiative or would like further information please contact or email us on the details below.

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New studies

ROSE

Rivaroxaban Observational Safety Evaluation

Background

The ROSE study is an observational post-authorisation safety specialist cohort event monitoring study (SCEM) to monitor the short term (first 3 months) safety and utilisation of Rivaroxaban (XARELTO®) prescribed for medical conditions requiring anticoagulation by specialists in secondary care in England and Wales. The study is being carried out by the Drug Safety Research Unit (DSRU), an independent registered medical charity.

Any adult patient in England or Wales can be included in the ROSE study after the clinical decision to prescribe Rivaroxaban or alternative anticoagulation therapy has been made. Following patient consent, the care team will be asked to complete an index questionnaire when treatment is commenced, then a second questionnaire 12 weeks later, using data recorded within the patient medical charts. No intervention will take place as part of this study.

Role of the GP

Although the ROSE study is recruiting patients whose treatment was initiated in secondary care, in those cases where the patient is referred back to the care of their GP before the end of the 12 week observational period, we would invite the GP to complete a 12 week follow-up questionnaire, by use of the patient's medical records. The questionnaires are largely tick-box style regarding treatment, concurrent medication, medical conditions and any adverse events reported. If a patient has an adverse event, completion of a further follow up questionnaire may be required. A payment of £50 will be made for a completed 12 week questionnaire. If a patient has an event requiring further follow up then we would pay £15 for follow up information provided.

Learn more

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Diabetes UK

Diabetes care in UK Universities (DRN727)

Norfolk and Norwich University Hospitals NHS Foundation Trust

Calling all GP practices serving university students

Are university students signposted to your practice on arrival at university?

If so we need you!

This is a multi-centre observational study, funded by Diabetes UK and is being conducted throughout the UK until June 2014. It is sponsored by the Norfolk and Norwich University Hospital. The Primary Care Research Network for Central England (Birmingham and the Black Country) has been asked to help with recruitment within primary care and we very much hope that you will support us with this very important piece of research.

Transitional care for young people with Type 1 diabetes (T1DM) is important, as many already have poor glycaemic control, psychological morbidity, and poor engagement with services. The further transition to university from school for young adults with T1DM can be a time of great disruption to family and clinical support.

We know little about the way that T1DM care is organised for school leavers in UK universities, how patients and professionals view diabetes services, or what the barriers are to good care. This study aims to provide a national review of diabetes services at UK universities and will identify what healthcare practitioners and young people with diabetes see as the major obstacles to improving diabetes care and engagement with health services. Once these obstacles are identified, the best existing clinical practices can be determined and communicated more widely and, if necessary, new and innovative ways of tackling problems can be explored.

We are asking diabetes healthcare teams in Birmingham to identify university students (school leavers undertaking a primary degree) aged 18-24 years old with T1DM. Once identified, they will be required to send out pre-prepared questionnaire packs to their patients. There is very minimal workload for GP practices and please note that if you are registered as a Research Site Initiative Practice this will count towards one of your study commitments. Practices taking part will be eligible to receive payment via service support costs to cover the time spent identifying and mailing out to eligible patients.

Learn more

If you would like to find out more and your practice serves university students within Birmingham, then please contact:

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TIRCON

A randomised, double blind, placebo-controlled trial of deferiprone in patients with pantothenate kinase-associated neurodegeneneation (PKAN)

The TIRCON study is a non-commercial study funded by the European Commission and ApoPharma (drug provision only). The Chief Investigator is Professor Patrick Chinnery, Newcastle University. The study will be investigating Panthothenate Kinase Associated Neurodegeneration (PKAN) and how to best treat the condition. It is commonly thought that the best way of treating the condition is to prevent the build up of iron within the brain; however the drugs available have been ineffective in achieving this. The aim of the study is to determine whether giving patients with PKAN the drug Deferiprone over an 18 month period can improve the symptoms and reduce the level of iron in the brain.

The main research site, Newcastle-upon-Tyne Hospitals NHS Foundation Trust, along with other Patient Identification Centre (PIC) sites across the country, will be identifying and recruiting patients aged 4 years to adult diagnosed with PKAN disease to participate in the study. They will consent all participants and randomise them to either receive a placebo or the study medication Deferiprone, which will be administered on site.

Participants will require a weekly blood test to check the haematological side effects of the drug. To minimise the inconvenience for patients they will be offered to have these weekly tests at their local GP practice if they do not live near Newcastle. Birmingham Children's Hospital NHS Foundation Trust will be identifying potential participants who may be patients of GP practices in the Birmingham and Black Country area. These GP Practices will then be informed in writing and asked to act as Research Follow-Up Sites to undertake the participant's weekly blood tests.

This is a Medicines for Children Research Network (MCRN) study that has been co-adopted by Primary Care. It will be recruiting 8 participants across the UK (who are likely to be children).

As part of the safety monitoring for the study the participants will be required to provide weekly bloods for a period of 18 months.

Once the participants have been approached there is a window of 60 days from the baseline assessment to the first safety blood sample being required to be taken. All other research activities will be happening off the GP practice premises. The blood samples will need to be taken by a suitably qualified person at the practice (GP, practice nurse or healthcare assistant) and this will take approximately 15 minutes. The blood samples will then be posted by the GP practice to the Royal Victoria Infirmary, Newcastle upon Tyne for processing in packs supplied by the research team.

GP practices will be informed in writing that a patient will be participating in the study. The practice will receive £5.40 for every blood sample obtained.

Learn more

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ACCU-RATE

How accurate are home blood pressure monitors used by patients?

'Accu-rate' is a NIHR funded cross sectional survey that aims to determine whether patients' own blood pressure monitoring equipment is sufficiently accurate to be integrated into daily practice.

It will ascertain which digital blood pressure monitors are currently used by patients, how well they perform, and whether there is any evidence of decreasing accuracy over time or with greater usage.

We would like to invite interested practices to contact us to take part. The additional workload is minimal. Service support costs will be reimbursed to cover recruitment.

Patients will be recruited from 8 practices across Birmingham.

Eligible patients on the hypertension register who currently self monitor with either a wrist or upper arm blood pressure monitor will be invited to attend device accuracy sessions at their own practices. Each monitor will be tested over a range of pressures, using standard calibration equipment and following a standard testing procedure as recommended by the British Hypertension Society. Machines with a difference in pressure of ≤3mmHg at all levels will pass. Each patient will receive individual feedback for their monitor.

Trial participation involves:

- Identification and screening of eligible patients using the hypertension register (health care professional)
- Mail a study invitation letter
- Receipt of monitors (frontline staff)
- Room hire

Learn more

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New studies

TASMINH 4

Telemonitoring And/or Self-Monitoring IN Hypertension

What is the TASMINH 4 trial?
This research is a patient randomised controlled trial to evaluate the management of hypertension in primary care using self monitored blood pressure values, with or without tele-monitoring, compared to that using clinic monitored blood pressure. It will also consider the effect of self-monitoring and tele-monitoring on adherence, side effects, quality of life, adverse events and costs. This study is being run by the Universities of Birmingham and Oxford underpinning key work from previous blood pressure surveys and TASMINH trials (TASMINH, TASMINH2, TASMIN-SR).

WE ARE LOOKING TO RECRUIT APPROXIMATELY 30 PRACTICES ACROSS THE WEST MIDLANDS THIS SUMMER.

What is involved for Practices?

- Practices will identify potential participants (patients with coded hypertension with a BP ≥140 (systolic) and/or 90 (diastolic) mmHg)
- Room hire for holding baseline and follow-up clinics (6 and 12 months)
- Mail study invitation letters to trial participants

Full training will be provided.

Practices undertaking this study will be eligible to receive payment via service support costs to cover the time spent recruiting patients.

Learn more
If your practice would like to take part or would like more information please contact:

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CPRD

Major new national research programme – your participation invited

The Clinical Research Network: Primary Care is fully committed to inviting all practices to join the Clinical Practice Research Datalink (CPRD), a secure, world-class, e-health research system jointly funded by the National Institute for Health Research (NIHR) and the Medicines and Healthcare products Regulatory Agency (MHRA) and we ask you to fully support this important initiative by enabling access to your practices' anonymised data for research.

Data Security and governance
Data security together with patient and practice confidentiality is of paramount concern to everyone and is CPRD's number one priority. CPRD uses the very highest standards of data security with robust information governance processes to ensure that patient confidentiality is maintained and data kept safe and secure at all times.

Sir Bruce Keogh, NHS Medical Director, and Sir Kent Woods, MHRA Chief Executive Officer who are the Caldicott Guardians of the NHS and MHRA respectively have both fully endorsed CPRD's data security arrangements.

What data is collected?
CPRD collects all coded data (diagnoses, treatments, referrals, lab results, demographics) against a CPRD identifier. CPRD does not receive NHS Numbers, names, addresses or postcodes.

Data downloads and your practice
CPRD is working with the major GP IT systems (Vision, EMIS, TPP) on data collection. The process of downloading data to CPRD is easy and will not interfere with existing systems or the normal day to day running of a practice. Data collections will happen automatically, requiring very little input from practice staff after the initial set up. The practice will not need to add any software to its systems.

Future Developments
The CRN: Primary Care are working with CPRD to help bring online a range of innovative software tools to support the increased efficiency of clinical trials. One such tool is a programme to help recruit patients onto clinical trials from primary care more quickly, easily and securely. Designed specifically to increase the efficiency of clinical trials and to help the CRN: Primary Care and the UK as a whole to remain at the forefront of medical research. Therefore, we encourage you and your practice to sign up to CPRD.

Learn more
To sign up or to ask additional questions please contact the team at:

CPRD Knowledge Centre
Email: kc@cprd.com
Telephone 020 3080 6383.
CPRD Website: www.cprd.com

Or alternatively please get in touch with the CRN: Primary Care:
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Health Informatics Specialist,
Keele University
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Current studies

A Study Promoting the Influenza Response in the Elderly (ASPIRE)

Vaccination against influenza (flu) is surprisingly unsuccessful, with many people failing to achieve the desired immunity after receiving their flu jab. This is a big problem in elderly individuals, for whom flu can be life-threatening. In addition the recent emergence of 'swine flu' has increased the danger of a new pandemic, meaning influenza remains a global health concern.

One reason that we develop immune 'frailty' as we age is that our bodies have to invest a lot of resources into fighting viruses that build up in us throughout our lives. One of these viruses is Cytomegalovirus, a member of the herpesvirus family.

In this clinical trial we will use medicine to reduce the amount of virus in the body, thereby decreasing the need for the body to fight this infection. We will test whether this in turn causes response to flu vaccination to improve. The study tackles a major clinical concern for UK health and could have major implications for the management of immune dysfunction in the elderly.

Design
This study is a two-phased randomised controlled trial. Part one will consist of a dose-finding study for the use of valaciclovir in suppression of the CMV-specific immune response. Once this information has been established we will implement the optimum dose and determine whether it leads to an improvement in the response to the seasonal flu vaccination in elderly people.

Aim of study
Phase I: The primary objective is to determine the efficacy of valaciclovir for reduction of both the CD4+ and CD8+ CMV-specific T cell responses.

Phase II: Aim is to assess the value of valaciclovir in the augmentation of the immune response to influenza vaccination in donors aged ≥65 years. This will then provide evidence as to whether a larger trial with clinical end points is justified.

Setting
This study will take place in the primary care setting, recruiting patients from NHS GP surgeries across Birmingham and the Black Country. Additionally, participants will be recruited from the Thousand elders groups of volunteers with the Wellcome Trust Clinical Research Facility being used to host clinics for these participants.

Target population
Healthy people aged 65 years and above, without significant chronic illness and not taking certain medication including anti-virals. Patients that fill these criteria will be screened, and if their blood tests pass various laboratory tests they will be eligible.

What the samples are being used for
At screening, blood samples are being used for several assays to test for eligibility for participation in the trial. At trial time points, blood samples will be used in assays to produce primary and secondary outcomes (ie, data that will form the results of the trial). A urine sample will also be taken at each time point, which will be used to measure the level of viral DNA.

Learn more

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GARFIELD-AF

Global Anticoagulant Registry in the FIELD

GARFIELD-AF (Global Anticoagulant Registry in the FIELD) is an observational, multicentre, international registry of newly diagnosed atrial fibrillation (AF) patients with at least one additional risk factor for stroke. The aim of the study is to evaluate the management and outcomes of patients with newly diagnosed non-valvular AF at risk of stroke. The registry aims to enrol 55,000 patients at more than 1000 sites in 50 countries. Enrolment will take place in five independent, sequential cohorts and patients will be followed up for a minimum of two years. Practices are remunerated per patient recruited. Enrolment to the third cohort is ongoing and in the UK, GARFIELD-AF is currently active in 142 practices in England, Wales, Northern Ireland and Scotland.

We have recruited 1745 patients to the registry so far. Thank you to all the practices participating in GARFIELD.

Learn more
If you would like further information about the study please contact:

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Current studies

BLISS

Birmingham Lung Improvement Studies

In response to the increasing burden of diagnosed and undiagnosed COPD in primary care and the need to identify, study and manage disease earlier (as highlighted in the COPD Outcomes Strategy), the University of Birmingham has been awarded a 5 year National Institute for Health Research (NIHR) Programme Grant for Applied Research programme. BLISS consists of three studies:

1. 'The Birmingham COPD Cohort Study – aiming to study prognosis in >2000 patients and create a primary-care based prognostic index'
2. 'A Randomised Controlled Trial of Targeted Case Finding for COPD versus Routine Practice in Primary Care (TargetCOPD)'
3. Occupational study to examine the effect of COPD on work (COPE).

The BLISS programme is currently active in 71 GP practices in the West Midlands and has recruited over 2,180 Patients to the Birmingham COPD Cohort Study, which is composed of patients with existing disease and newly diagnosed patients, invited through the TargetCOPD case-finding trial. The Birmingham Cohort Study has a 3 year patient follow up, which will commence next year.

The TargetCOPD project is in the final phase and all practices will be closed by June. We have assessed more than 2500 patients and their spirometry results have been fed back to GPs to identify new cases.

The occupational sub-cohort has been a great success, identifying more than 250 patients currently in work. We are commencing our novel occupational intervention feasibility study in the next month.

We would like to give a warm Thank you to all those practices who have taken part in the BLISS programme, your partnership has made the programme a big success.

Professor Peymane Adab and Professor David Fitzmaurice are Chief Investigators for the BLISS Programme. Dr Rachel Jordan, Senior Lecturer at the University of Birmingham is co-chief investigator for TargetCOPD Case finding trial.

This article presents independent research commissioned by the National Institute for Health Research (NIHR) under {insert name of programme}. The views expressed in this publication* are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

CANDID

CANcer DIagnosis Decision rules

The CRN: Primary Care is looking for expressions of interest from GP practices to be involved in this national non-commercial study. This is an extremely important piece of work and an opportunity for both patients and doctors to be involved in research to look at the way clinical decisions are made for lung and colorectal cancers. Key areas of concern for both doctors and patients in primary care when suspecting a patient has cancer are preventing delays in diagnosis, getting high risk patients referred first and keeping unnecessary investigations to a minimum.

CANDID is an observational cohort study recruiting patients opportunistically via GP consultation and in addition, from late February, undertaking a monthly database search. We are grateful to our local GPs who have already arranged an information visit with the study team. We are delighted to report that, so far, we have had a very positive response to the study resulting from these visits.

Ideally we need to recruit a total of 50 practices. Currently 23 GP practices have expressed an interest, which is a fabulous response. However, we would like to identify more practices in Birmingham and the Black Country to take part in the study. Nationally the study is hoping to recruit 10,000 patients for each condition. The study will be recruiting participants until September 2015 with a short notes review 2 years following recruitment. Practices undertaking the study will be eligible to receive payment via service support costs to cover their time spent recruiting patients. As well as GPs, potentially this is an ideal study for trainee GPs in your practice to be involved in research. Additional payments will be made for any blood samples taken.

Learn more

For further information or to express an interest in taking part in this study please contact:

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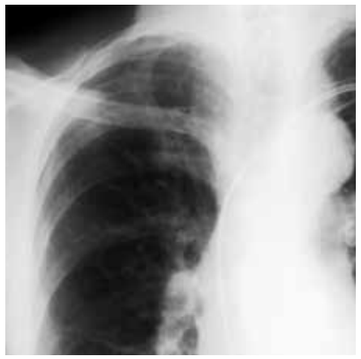

ExACT

Extended Anticoagulation Treatment for VTE: a randomised trial

Background to trial

Venous thromboembolism (VTE) is common with an incidence of approximately 1 per 1,000 per annum. It is associated with significant mortality and morbidity, including post-thrombotic syndrome (PTS). The annual recurrence rate following a first VTE is approximately 10% per annum irrespective of the duration of warfarin therapy.

This suggests that some patients should continue warfarin long-term. However, currently we are unable to identify this population.

Aim of trial

To investigate whether extending treatment with warfarin beyond 3-6 months, for patients with a first unprovoked proximal DVT or PE, reduces the recurrence rate.

We still need your help! To recruit patients, aged over 18, with a first unprovoked VTE from both primary care and secondary care anticoagulation clinics.

To date, 208 patients have been enrolled into the trial. Recruitment will continue until 28 February 2015, and patient follow up will continue until February 2017.

Although recruitment is well under way we still need **more** patients and help from GPs.

We are in touch with GPs in your area asking for help with confirmation of patient's eligibility for inclusion into the study and provision of a room for the 2 year follow up.

There is a reimbursement for these services. If you are already involved please don't forget to let us know if an ExACT patient experiences any adverse events.

Trial Intervention

Patients receive brief information about the study and are given a postcard to return to the research team if willing to take part. Patients are randomised to either continue or discontinue warfarin and will be followed up every six months for two years. We will be looking at D-dimer levels (a product present in the blood after a blood clot), the development of PTS and associated quality of life. We are also looking at the cost effectiveness of continuing warfarin treatment for these patients.

Learn more

If you are interested in getting more involved or require further information then please contact:

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BARACK-D

Benefits of Aldosterone Receptor Antagonism in Chronic kidney Disease Trial

Objectives

To determine whether the addition of an aldosterone receptor antagonist (ARA) in patients with moderate Chronic Kidney Disease (CKD):

- Reduces death
- Reduces onset or progression of cardiovascular disease
- Improves measures of vascular resistance
- Improves left ventricular function
- Reduces decline in renal function

Background

Better treatment options providing protection from vascular events or delaying progression of CKD are urgently needed.

There are limited therapeutic options to reduce overall cardiovascular risk in CKD. Accumulating data suggest ARAs may offer cardio-protection and delay renal impairment in some patients.

BARACK-D is the only current large prospective randomised open blinded endpoint trial (PROBE) focussing on this theme.

Recruitment

120 practices are being recruited nationally.

22 practices are needed in Birmingham and the Black Country.

Patients will be identified by their GPs with a diagnosis of CKD stage 3b and will be invited to take part.

Participation

Patients will be followed up for 36 months and will be randomised to either:

a) Treatment plus standard care
b) Standard care alone

Practice remuneration is available.

Learn more

For further information, please contact:

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Current studies

Helicobacter Eradication Aspirin Trial

Helicobacter eradication to prevent ulcer bleeding in aspirin users: a large simple randomised controlled trial

Principal Investigator Birmingham Region:
Prof Richard Hobbs

Locations: ~400 GP practices in Birmingham and the Black Country, Worcestershire, Coventry and Warwickshire, Shropshire, Staffordshire, Herefordshire, Stoke, Telford and Wrekin, Wolverhampton, Nottingham, Durham, Southampton, and Oxford.

Enrolment Period: 2012–14

Participants:
Men and women aged 60+, infected with H. pylori, who are using aspirin <326mg daily

Other Information:
This trial has been preceded by a successful pilot study, funded by the MRC. Practices will be reimbursed for their time.

Use of aspirin for cardiovascular prophylaxis is widespread and increasing. The main hazard is ulcer bleeding. This is usually associated with H. pylori infection. It is important to determine whether this can be reduced or prevented by H. pylori eradication. The trial hypothesis is that aspirin does not itself cause peptic ulcers, but that it promotes bleeding of ulcers caused by H. pylori. Given the scale of aspirin use, its continuing increase and its contribution to ulcer bleeding, how to deal with this problem is arguably the most important question with regard to current iatrogenic medicine.

Intervention and Clinic:
Suitable patients will be identified by their surgery, using an automated search, and then asked to attend an appointment with a University Research Nurse or Practice Nurse (relevant training will be provided) to consent to the trial and take a H. pylori breath test. Those with a positive result will be randomised to receive a one week course of either eradication treatment or placebo, supplied by the trial centre. No follow-up visits for the patients are required, but any hospital admissions for ulcer bleeding will be recorded over a period of 2-3 years by the trial centre.

Learn more

If you would like to find out more, please contact the Trial Manager for your region:

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MNDA

Motor Neurone Disease Association

An Epidemiological Investigation of Motor Neurone Disease

This study is addressing environmental factors that are contributing to disease in individuals with Motor Neurone Disease (MND) with a view to enhance understanding of disease mechanism and improve treatment. Professor Karen Morrison's team at University Hospital Birmingham are recruiting patients with MND from outpatient clinics. They will be matched with Controls (no MND) from general practice, for age, gender, ethnicity and geographical region. We currently have some practices in Birmingham working with us to identify the last batch of required controls for this study. Thanks to all the practices that have assisted with this over the duration of the trial as they have been crucial to the success of the study as a whole.

Learn more

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OSAC

Oral Steroids for Acute Cough Trial

Chest infections affect most people every year. OSAC is a randomised controlled clinical trial to find out whether oral steroids could be a better treatment than prescribing antibiotics, which contribute to the rise of serious hospital infections like MRSA. OSAC is funded by the NIHR and has received NHS ethical approval. The study is being run by the Universities of Bristol, Oxford, Nottingham and Southampton.

The OSAC trial will test whether 40mg of oral Prednisolone daily for 5 days will reduce the duration and severity of moderately bad (or worse) symptoms associated with acute chest infections by at least 20%, compared to placebo. A relatively high dose has been selected to maximise the chances of the study detecting an effect. But if beneficial effects are found, lower and inhaled doses of steroids would be tested in the future.

We recruited the required 4 practices for this area and they have started to recruit for the study. Two of these practices are based in Sandwell and West Birmingham, one in Solihull and the final practice is from Birmingham Cross City CCG. So far we have 4 patients recruited. We are delighted to report that our first practice achieved their first patient recruited within 30 days target.

The results of this study could help to give clinicians a new treatment option that could substantially improve health, reduce the inappropriate prescribing of antibiotics, and contribute to a growing body of research investigating the effects of steroids on the undesirable inflammatory symptoms associated with infection.

Learn more

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The Preloading Trial

Help your patients to quit smoking.

Don't miss this opportunity to help more smokers in your practice quit. The University of Birmingham are recruiting smokers to take part in an NIHR HTA funded trial of nicotine patch preloading, and we are looking for interested GP practices to get involved by writing to smokers at their practice and offering them our support to quit.

Although participants who use the NHS Stop Smoking Service are four times more likely to quit than those that quit alone, the majority will still return to smoking. Therefore we need to find new, effective treatments to help people to quit. Nicotine preloading is the use of nicotine patches by smokers before quitting, whilst smoking as usual. There are a number of reasons why this may help someone to give up smoking, including the following:

1. It may help to break the association between smoking and reward, making quitters less likely to relapse.
2. If people feel less pleasure whilst smoking with the patch on then this may make them feel more confident that they can quit.
3. Consuming nicotine through using patches and smoking (although not harmful) may result in some unpleasant sensations, such as nausea. This could lead to an association between smoking and negative feelings, making the smoker less likely to want to smoke.
4. Using the patch before quit day could get the participant used to using the medication, so that they are more likely to use it successfully post-quit day.

We carried out a meta-analysis to investigate whether nicotine preloading is advantageous, however this was largely inconclusive, with some studies finding a large positive effect and some not. Therefore we concluded that more research is needed to investigate the treatment.

The Preloading Trial is a large multi-centre trial, recruiting through centres in the West Midlands, Nottingham, Bristol and London. We need GP practices to write to smokers registered with them to see if they would like to take part. Eligible participants will then be randomised, either to receive 4 weeks of nicotine patch preloading, or not. The research team will need to see participants for two weeks at their practice before referring them to their local NHS Stop Smoking Service (which could be a service already operating in the practice) for standard support. Our primary outcome measure is the participant's smoking status at 6 month follow-up. To collect follow-up data the research team will also need to see those participants claiming to be abstinent at 6 month and 12 month follow-up, at their practice.

Practices taking part will be required to write to their list of registered smokers to invite them to the study and provide a room for use by our researchers one day (or morning/afternoon) a week. All of your costs in taking part will be covered and the study could help your patients to give up smoking. Therefore, if you are based in the West Midlands and would like to be involved then please contact:

Learn more

Mike Healy
Research Administrator
Tel: 0121 415 8019
Email: m.healy@bham.ac.uk;

Current studies

PSM COPD

Patient Self-Management in primary care patients with Chronic Obstructive Pulmonary Disease (PSM-COPD)

PSM-COPD is funded by the National Institute for Health Research, School for Primary Care Research. It is a multi-centre study that is taking place across 4 UK Centres including; Birmingham, Oxford, Manchester and Keele. To date, 18 practices have been recruited across Birmingham and the Black Country. The study will be recruiting until September 2014 and the study team is still looking to recruit additional practices.

Why is this research being carried out?
There is an absence of research evidence regarding the effectiveness of self-management interventions in primary care for people who report only mild symptoms of their COPD. Recent interest in COPD case finding in primary care, driven by the new National Clinical Outcomes Strategy for COPD, will result in identified patients who are not eligible for pulmonary rehabilitation. This study aims to inform care for this patient group and potentially slow the progression of their condition by advising lifestyle changes.

Aim of the study
The research aims to determine whether a telephone-based self-care intervention for people with COPD who display symptoms of mild dyspnoea, improves health-related quality of life and health behaviours at 12 months follow-up, compared to people allocated to usual primary care.

Practice involvement
- Conduct practice database search to identify potentially eligible patients
- GP to check list and prescribe bronchodilator used for spirometry
- Send out postal invitations to identified patients; materials and costs associated with this will be provided
- Provide a room and facilities for research clinics
- Please note that practice staff WILL NOT have to administer any questionnaires, book appointments for study clinics or train patients in self-management

Benefits to the practice in taking part
- The study will assist with COPD QOF targets (COPD002, COPD003, and COPD004)
- Spirometry assessment for your patients who are MRC1 and 2
- Updated BMI for your patients according to NICE guidelines
- All costs will be reimbursed in the usual way, according to the level of involvement of the practice.

Learn more
We would be very grateful for your support and involvement in this study. For further information, please contact:

Sarah Campbell
Senior Facilitator, CRN: Primary Care
Tel: 0121 414 3168
Email: s.l.campbell.1@bham.ac.uk

REVISE-Diabesity

Effective treatment options for combined diabetes and obesity, sometimes called ‘diabesity’, are fairly limited.

REVISE-Diabesity aims to evaluate, in an NHS Secondary Care setting, the metabolic effectiveness of Endobarrier alone versus combined Endobarrier-Liraglutide therapy in patients with obesity and type 2 diabetes mellitus who remain overweight and with sub-optimal glycaemic control despite Liraglutide treatment.

The Endobarrier is a new device for diabetes, which mimics the ‘bypass’ aspect of gastric bypass surgery using an endoscopic approach. There will be a 1 year treatment period with an additional 12 month follow-up period.

We are asking practices in Birmingham to act as Patient Identification Centres (PICs) for this study.

Learn more
If you require further information please contact:

Sarah Hadfield
Research Facilitator, CRN: Primary Care
Tel: 0121 414 8045
Email: s.hadfield@bham.ac.uk

Validation of home blood pressure monitors in patients with atrial fibrillation

This research aims to determine if automatic blood pressure (BP) monitors, already independently validated to take measurements in the home environment and shown to be amongst the most accurate in the general population, can be reliably used in patients with Atrial Fibrillation (AF).

No automatic BP monitors are currently validated for use in AF. If monitors are shown to take accurate blood pressure readings in patients with AF, the use of home BP monitoring could be recommended in this high risk group to improve the effectiveness of hypertension diagnosis and management. Home BP monitoring allows many more BP readings to be taken, and therefore might help provide a more accurate picture of the true underlying BP levels in AF patients.

The proposed research will assess the potential of home BP monitoring in AF through validation studies of different home BP monitors in patients with AF to assess their accuracy in this population. This will include additional analysis of the minimum number of measurements required before we can be confident in the accuracy of the obtained BP values for AF patients. Devices will be validated against standardised protocols to ensure consistent and reliable assessment.

Eligible patients, recorded as having permanent chronic AF, will be invited to participate. The validation studies will follow the standard British Hypertension Society (BHS) and European Society of Hypertension International Protocol (ESH-IP) protocols, and will take place in the NIHR Wellcome Trust Clinical Research Facility in Birmingham. This facility accredited by the BHS as a site for monitor validation, and where validation studies are regularly conducted.

We are looking to recruit up to 10 practices through 2014, and would like to invite interested practices to contact us to take part or for further information. The additional workload is minimal and service support costs to cover time recruiting patients will be reimbursed.

Study participation involves:
Identification and screening of eligible patients
Mail-out of study invitation letter

Learn more
Dr James Hodgkinson
Research Fellow
Tel: 0121 414 8842
Email: j.a.hodgkinson@bham.ac.uk

VTEC

A prospective observational study of care home residents to determine the incidence of VTE among care home residents

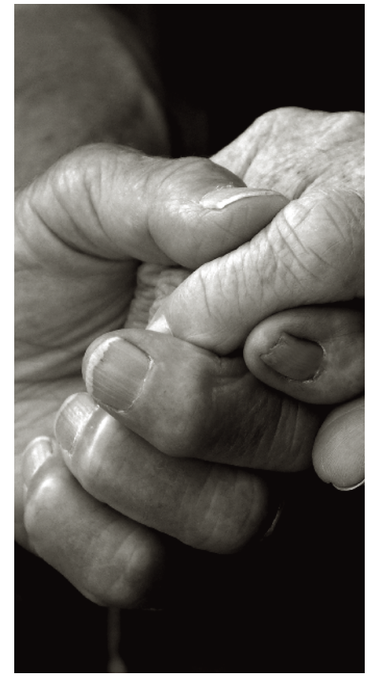
Venous thromboembolism (VTE), consisting of deep vein thrombosis (DVT) and pulmonary embolism (PE), is a relatively common condition associated with serious outcomes. Around 60,000 deaths a year in the UK are due to VTE and around 50% of these are acquired in hospital. Although the clinical benefit of prophylaxis for VTE in hospitals is known, in the care home setting we have little understanding of firstly the incidence of VTE, and secondly VTE prevention and treatment strategies.

This study will determine for the first time the incidence of VTE among care home residents in the UK. The study is observational and aims to recruit 1000 care home residents in Birmingham and Oxford. GPs caring for enrolled patients will also be recruited to the study in order to access participants GP notes. Care home residents who have been consented to the study will undergo two case note reviews of their care homes and GP records, comprising of a baseline assessment and a follow up assessment one year after enrolment.

We are currently approaching GPs of enrolled residents in the Birmingham area so we may be contacting your practice. The only involvement of the practice is to allow the research team access to the participants GP records to undertake the notes review. Alternatively practice staff may conduct the notes review and complete the case report form. There will be a payment for your involvement.

Learn more
If you would like further information about the VTEC study please contact:

Patricia Apenteng
Research Fellow
Tel: 0121 414 8579
Email: p.n.k.apenteng@bham.ac.uk



In Follow Up

STOP-CKD

Spironolactone to Prevent Cardiovascular Events in Early State Chronic Kidney Disease: A pilot Trial

STOP-CKD is a double-blind placebo controlled randomised pilot study. The study is examining what effect Spironolactone has on arterial stiffness in Chronic Kidney disease (CKD) patients.

Increased arterial stiffness is shown to be a crucial change in CKD and is strongly associated with cardiovascular mortality and morbidity. This risk factor and left ventricular (LV) hypertrophy are present in CKD patients independent of good blood pressure control. We have already shown in secondary care that spironolactone therapy in early CKD patients safely and effectively reduces LV mass and arterial stiffness.

As early CKD is common and most patients never attend a renal clinic, we wish to assess whether spironolactone reduces arterial stiffness in CKD stage 3 patients recruited in primary care and assess the safety of this drug, for example the rates of hyperkalaemia and deteriorating renal function. In addition, we will also evaluate patients' and healthcare professionals' attitudes towards such treatment as a prelude to a much larger trial with clinical end points (cardiovascular events). This is a collaborative study between the PC-CRTU at the University of Birmingham and the Department of Nephrology at the Queen Elizabeth Hospital. As spironolactone is off patent and therefore of no interest to the pharmaceutical industry, we have gained funding for our study from the National Institute of Health Research.

The study is currently active at GP practices in Birmingham and in its final stages of screening, which we aim to have completed by early March. Patients randomised to the study will be followed up at 2, 4, 8, 16, 28 and 40 weeks with a post study final review at 46 weeks by the study team that is led by Consultant Nephrologist, Dr Charles Ferro.

Learn more

If you have any queries or would like further information please contact us on:

Val Redman
Trial Co-ordinator, PC-CRTU
Tel: 0800 9230329

3C – Cough Complications Cohort study

The aim of the 3C study is to determine if the development of severe complications (ie, pneumonia that requires hospitalisation) can be predicted in patients seeing their GP with a cough and suspected chest infection. The study opened for recruitment in September 2009 and information from over 31,000 patients' symptoms, their medical history and a number of clinical measurements were recorded by the GP or extracted from patient records.

The study surpassed its original target and closed for recruitment in December 2013. The West Midlands was the second highest recruiting area and contributed over 3,000 participants towards the target. Given the national and local achievements for this study, the Clinical Research Network: Primary Care acknowledged the contribution of the top three recruiting sites in Birmingham and the Black Country. Plaques were awarded to Maypole Health Centre who recruited 267 patients, Eve Hill Medical Practice who recruited 117 patients and Woodgate Valley Health Centre who recruited 85 patients.

Although these practices were presented with plaques, it is the contribution from all 37 GP practices in the Birmingham and Black Country area that has made this study a success. Max Feltham, Research Manager for CRN: Primary Care said: 'This is a fantastic achievement for Primary Care Research in Birmingham and the Black Country. It demonstrates how the Clinical Research Network is reaching out to patients across the area and how GPs in Birmingham and the Black Country are contributing to national research.'

The data will be analysed to find out which factors predict who is likely to develop severe complications. We will provide a summary of the findings when they are made available by the study team based at the University of Oxford.

Max Feltham
Research Manager
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Email: m.g.feltham@bham.ac.uk

1st place – Maypole Health Centre

2nd place – Eve Hill Medical Centre

3rd place – Woodgate Valley Health Centre

NHS
National Institute for Health Research

West Midlands
Research Design Service

What is the RDS?

The RDS exists to provide help to people preparing research proposals for submission to peer-reviewed funding competitions for applied health or social care research. The RDS essentially consists of a team of methodologists based in universities and the NHS across the West Midlands, able to advise and provide practical support when you are developing your grant application. As the RDS is funded by the NIHR for this purpose, such help is provided free of charge.

Who can use the RDS?

The RDS will provide advice to NHS researchers, and others working in partnership with the NHS, who are developing research proposals for submission to national, peer-reviewed funding competitions.

For more information on West Midlands RDS please contact Melanie Guthrie on 0121 414 8533 or rdscentre@contacts.bham.ac.uk

www.rds-wm.nihr.ac.uk

How can the RDS help me?

The RDS can advise on all aspects of preparing grant applications,

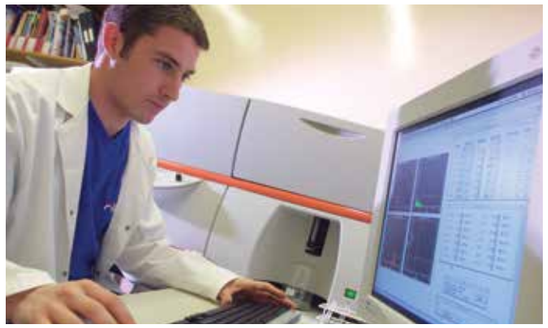
- Formulating research questions
- Building an appropriate research team
- Involving patients and carers
- Designing a study
- Appropriate methodologies for quantitative research, eg, statistical issues, health economics
- Appropriate methodologies for qualitative research, eg, sampling, analytical strategies
- Identifying suitable funding sources
- Regulatory issues
- Writing lay summaries
- Identifying the resources required for a successful project

Advice and support is best provided face-to-face. RDS staff will be happy to meet with you at a convenient time and place to discuss your research. It is preferable to contact us at an early stage to discuss your ideas.

Study results

Attitudes towards bariatric surgery and research participation amongst non-morbidly obese patients with type 2 diabetes

This is an NIHR, Research for Patient Benefit (RfPB) funded study investigating patient and clinician perspectives on weight management for non-morbidly obese people with type 2 diabetes, specifically with regard to the role of and willingness to participate in future randomised, controlled trials. The study had 2 phases, the first involved qualitative interviews with patients, whilst the second phase used interview data to develop a patient survey which was mailed out to 1820 non-morbidly obese patients with type 2 diabetes. We also surveyed primary care diabetes leads (GPs and Nurses), diabetologists and bariatric surgeons. Fourty-four GP surgeries participated and provided invaluable support in identifying and recruiting eligible patients to one or both of these phases. Below summarises the results for each phase of the OCOD study.



Phase 1: Patient views on the role of bariatric surgery (qualitative interview study)

Twenty-two patients were interviewed. Willingness to consider WLS as a personally acceptable management option was variable, ranging from those who were willing (N=4) to consider surgery or undecided (N=5), to those who were unwilling (N=13).

Acceptability of WLS: Two factors seemed influential in those who adopted a willing or undecided stance towards surgery; condition-related impact (the extent to which either their diabetes and/or weight affected their life) and their perception of control over their diabetes and/or weight.

Condition-related impact: Some individuals felt that neither their weight nor their diabetes affected their lives, and these people were unwilling to consider surgery. Conversely, those who were willing or undecided all noted that their weight and/or diabetes adversely affected their lives.

Perceived control: Some individuals were dissatisfied with the effect of their weight and/ or diabetes on their lives but still felt surgery was inappropriate for them. In such cases the individual's sense of personal control seemed influential with those unwilling reporting some capacity to alter their situation. In contrast, those who reported being unsure or willing to consider surgery reported having tried numerous strategies and being unable to lose weight themselves.

Participating in randomised controlled trials: Those who were 'undecided' or 'interested' in WLS were more willing to consider entering into an RCT than those who were not interested in surgery.

The information collected in this phase informed the content of the patient survey and the perceptions entered into later statistical analyses of survey responses.

Dissemination: To date we have presented this work in a poster at the North American Primary Care Research Group (NAPCRG) and have submitted a paper to the Primary Health Care Research and Development journal.

Phase 2a: Patient views on the role of bariatric surgery in their management (survey study)

34% (614/1820) responded. 72% were interested in participating in general weight management research; this was not specific to surgery and included any form of weight management. In relation to participating in a randomised controlled trial (RCT) which involved bariatric surgery 64% said that they would be willing to consider entering.

We undertook analyses to ascertain whether there were differences between those who were willing to participate in RCT research and those who were not. There were significant differences (P=<0.005) in perceived control, satisfaction with weight loss ability and impact of diabetes/ weight on life.

A greater proportion of those willing to consider entering into a trial reported:

1. Less control over their diabetes (Fig.1)
2. Dissatisfaction with their ability to lose weight (Fig.2)
3. Weight negatively impacting on life (Fig.3)
4. Diabetes negatively impacting on life (Fig.4)

These perceptions were entered into a regression analysis (logistic) to assess whether any were predictive of willingness to participate. The analysis indicated that only age (younger more likely), negative impact of weight on life and being unsatisfied with ability to lose weight were significant. Being on insulin was not shown to be influential in willingness to participate in bariatric RCTs.

Dissemination: To date we have presented our findings at the Society for Academic Primary Care (South West) Conference, and at the Endocrinology, Nutrition and Metabolism seminar, University of Southampton. The study has been well received and has generated positive feedback. We have recently submitted an abstract of the above results to the British Obesity and Metabolic Surgery Society (BOMSS). An initial paper has been drafted with a view to submitting to Diabetes Care after further iterations.

Phase 2a Figures

Figure 1

How able are you to control your diabetes?

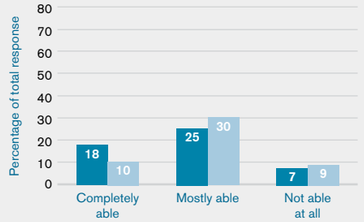


Figure 2

How satisfied are you with your ability to lose weight?

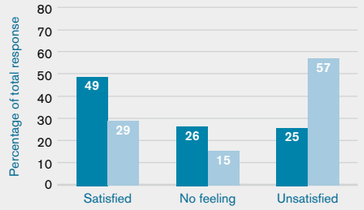


Figure 3

Does your weight negatively impact on your life?

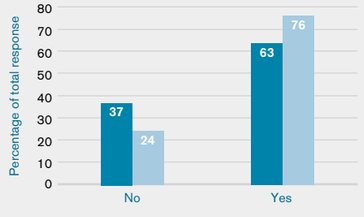
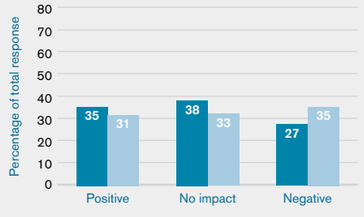


Figure 2

Overall, what impact has diabetes had on your life?



Consider RCT No Yes

Phase 2b: Clinician views on the role of bariatric surgery in the management of non-morbidly obese patients with type 2 diabetes

31% of surgeons (42/138), 15% of primary care clinicians (104/700) and 6% of diabetologists (35/600) responded. There was interest in participating in an RCT involving WLS amongst respondents, with 97% of surgeons, 90% or diabetologists and 74% of primary care leads answering 'yes' or 'maybe'. However, we have no data by which to assess non response and the number of responses was too low for meaningful statistical analysis to be conducted. Unfortunately, we are unable to draw firm conclusions with regard to clinical equipoise/ interest in bariatric RCTs.

Despite efforts to increase response rates, including working with clinical groups, piloting surveys and survey mediums and sending reminders, a key barrier which prevented adequate recruitment to the clinician survey related to difficulties accessing clinicians.

Dissemination: We have recently submitted an abstract of the above results to the British Obesity and Metabolic Surgery Society (BOMSS) and also intend to submit to next year's Society for Academic Primary Care (South West) Conference.

Study Conclusions

Overall, 64% (379/614) of patients were willing to consider participating in a WLS trial. Factors significantly and independently associated with willingness were younger age, negative impact of weight and dissatisfaction with ability to lose weight. Owing to methodological barriers we were unable to evaluate equipoise and interest amongst clinicians.

Future plans

1. To publish the patient survey in an appropriate peer reviewed journal (Diabetes Care)
2. As a result of the interest identified in this study, we aim to develop a model to estimate the potential costs and benefits of WLS in non-morbidly obese patients with T2DM to help justify the value of information from a definitive trial.
3. To submit a case for an RCT to NIHR HTA prioritisation process, and design a trial of WLS in this population which would provide much needed evidence on the effectiveness and cost utility.

What's new in CPD this coming year at University of Birmingham?

Ongoing Courses 2014–15

PGT MSc 10 or 20 credits

Anticoagulation management in primary care

16–18 June; 15–17 September; 1–3 December 2014

This three day module aims to ensure safe practice managing with both fundamental and more complex problems of oral anticoagulation management.

Other modules available 2014–15

- Atrial Fibrillation Management and Stroke Prevention — 24 – 26 November 2014
- Management of Heart Failure in primary care — 26 –29 January 2015
- Management of Hypertension in primary care
- Management of Gynaecology in the community
- Mental Health Care in the Community

Continuing Professional Development

An Introduction to Oral Anticoagulation Management

9 June; 8 September; 17 November 2014

This one day course for practice nurses and GPs aims to provide an overview of the management of oral anticoagulation.

Management of DVT and Pulmonary Embolism within primary care

10 June 2014

This one day course aims to provide expertise on the diagnosis and management of DVT within a primary care setting and to inform on major developments around VTE prevention for patients admitted to hospital.

Oral Anticoagulation Management for Health Care Assistants and Assistant Practitioners

11 June; 15 October 2014

A very popular one day course aimed at health care assistants and assistant practitioners working within anticoagulation clinics. We provide a basic knowledge of safety issues in anticoagulation management, INR testing technique, quality control and patient education.

Anticoagulation in Practice 2014

5 – 6 June 2014

General practitioners, practice nurses, cardiologists, haematologists, biomedical scientists, pharmacists and patients are all invited to attend the eighth scientific meeting of Anticoagulation in Practice 2014 at the Wolfson Centre, University of Birmingham.

We have a very exciting programme for 2014; day one will focus on management of Atrial Fibrillation and day two, venous thromboembolism. We are delighted to announce that our 2 keynote speakers will be Dr Campbell Cowan, Chair of the NICE Guideline Development Group for Atrial Fibrillation and Professor Susan Kahn, the world's leading researcher in post thrombotic syndrome and venous thromboembolism from McGill University.

Diagnosis and Management of Headache Disorders in Primary Care

14 November 2014

This one day course aims to provide an evidence based approach to the challenges of diagnosis and management of headaches. It provides a unique opportunity to interact with the experts on a wide range of causes of headache.

Liver disease in primary care

20 – 21 November 2014

This two day mini conference organised in conjunction with Dr Phil Newsome, Hon Consultant Hepatologist, Queen Elizabeth Hospital Birmingham and other national leaders in Liver disease care.

The course aims to provide both theoretical and practical knowledge of liver disease and how to manage within a primary care setting e.g. alcohol use and common liver disorders.

Please see the conference website for further information: www.birmingham.ac.uk/aip2014

Coming soon

Patient self-monitoring of Oral Anticoagulation

This one day course aims to provide an education framework for health professionals requiring the tools for training patients in self-testing or management of oral anticoagulation.

Understanding Haematology tests – when to refer

This one day course aims to cover the following areas of haematology; red cells and haemoglobin, white cells, platelets and coagulation, the common laboratory tests used, how to interpret them and parameters at which referral to a haematologist is indicated.

Details of all modules and CPD courses are available on our website: www.birmingham.ac.uk/anticoagulation

For further details please contact

Amy Partleton
Postgraduate Course Administrator
Tel: 0121 414 2677
Email a.partleton@bham.ac.uk

Tamara Ball
CPD Course Administrator
Tel: 0121 414 3281
Email: t.c.ball@bham.ac.uk

NHS National Institute for Health Research

Keep *In Contact*

Primary Care Clinical Research & Trials Unit · Networks · CTU · Primary Care · PC-CRTU

Interested in taking part in research? We'd like to hear from you.

- You will always be able to choose your practice's level of involvement.
- You will be remunerated for practice time spent on research.

Contact details:

Name:

Job title:

Practice address:

Postcode:

Practice code:

Email:

Your email address will only be used to send you details of studies being undertaken by the Primary Care Clinical Research and Trials Unit, Clinical Research Network: Primary Care and Primary Care Clinical Sciences Department.

The Primary Care Clinical Research and Trials Unit (PC-CRTU) works in conjunction with the Clinical Research Network: Primary Care, part of the National Institute for Health Research (NIHR). Only studies which have been independently peer-reviewed and funded through national competition; and commercial research asking relevant questions will be adopted onto the NIHR Portfolio of studies.

You can:

Fax back this form to **0121 414 2282** or
Email the details above to pccrtu@contacts.bham.ac.uk or
Phone us on **0800 085 4229** for further information.

Alternatively, send the completed form to our postal address, as detailed on the back page.

Funding available for you and your GP practice to support the Research Sites Initiative

NHS
National Institute for Health Research

Clinical Research Network
Primary Care

The CRN: Primary Care is rolling out a new initiative in the Birmingham and Black Country area called the Research Sites Initiative (RSI). This new annual initiative aims to strengthen the research infrastructure and the CRN: Primary Care would like to invite you and your practice to participate.

What is RSI?
The RCGP and the CRN: Primary Care have developed the Research Sites Initiative (RSI) which is open to all practices. This is a standardised pathway, which makes funding available to you and your GP practice. It will establish and maintain capacity and capability for you and your practice to contribute to NIHR portfolio research.

How it works
You are invited to apply for membership and, if successful, you and your practice will be allocated funding to cover research infrastructure costs in addition to NHS support costs (SSC). In return for this support your practice will need to meet specific research-related requirements such as Good Clinical Practice (GCP) training, RCGP Research Ready accreditation and contributing to a minimum number of portfolio and commercial studies. The RSI offers two levels of involvement.

Is RSI the same as Research Ready?
No, the Research Ready Scheme is an arm of the RSI, which will eventually be phased out.

Practice levels and Remuneration
There are two levels of RSI to match your practice's research experience

Level 1 – Remuneration £1000
- Complete the online Research Ready accreditation
- Meet the specific research requirements (GCP)
- Attendance at an annual Network meeting
- Participate in a minimum of 2 NIHR Portfolio studies (SSC's will continue to be paid)

Level 2 – Remuneration £2000
- Same as Level 1 and
- Participate in a minimum of 3 NIHR Portfolio studies (SSC's will continue to be paid)

NHS Support Costs
NHS support costs (SSC) will continue to be paid to cover all agreed research activity you and your practice contribute towards NIHR portfolio research.

If you and your practice would like to apply for this new initiative or would like further information please contact or email us on the details below.

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Sarah Campbell
Senior Facilitator
Tel: 0121 414 3168
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Edgbaston, Birmingham B15 2TT

Visit our website
www.birmingham.ac.uk/pc-crtu

General Enquiries
Tel: 0121 414 8843
Fax: 0121 414 2282

Randomisation Service
We now offer a telephone randomisation service for studies. Contact us for further details on 0121 414 8532