SPIRO-CKD Newsletter

A Randomised Multicentre Open Label Blinded End Point Trial to Compare the Effects of Spironolactone to Chlortalidone on Left Ventricular Mass and Arterial Stiffness in Stage 3 Chronic Kidney Disease

Issue 1 | **July 2014**

In this issue:

Welcome to the first issue of the SPIRO-CKD Newsletter!

A very warm welcome to the first issue of the SPIRO-CKD Newsletter. We are delighted to tell you that two of our collaborating sites (Birmingham and Edinburgh) are now open to recruitment and our first patient was recruited in June 2014 at University Hospitals Birmingham. Cambridge is scheduled to open in July and trial setup in London is progressing apace.

UNIVERSITY OF BIRMINGHAM

BIRMINGHAM CLINICAL TRIALS UNIT

British Heart Foundation

Message from the Chief Investigator

Dear Colleagues,

I am absolutely delighted that after over two years work since the genesis of the SPIRO-CKD trial, which is supported by the BHF, we have progressed to the point where two centres (Birmingham and Edinburgh) are recruiting. The other two are rapidly approaching this stage. We have recruited three patients here in Birmingham so far and hit only minor teething problems.

As we enter the exciting phase of patient recruitment (only 347 patients and about 90 weeks to go!). I greatly look forward to working with you to deliver the answers required to the important questions we are addressing. The study is challenging in some respects but I am sure all the team members will work hard to ensure its success.

Please feel free to contact me or Gemma (spiro-ckd@trials.bham.ac.uk) if you have any questions regarding the study.

Best wishes,
Prof Jon Townend

Trial Design	Aims
Prospective, randomised, open-label, blinded-endpoint (PROBE) study design	• To assess the change between baseline and 40 weeks in arterial stiffness measured by carotid-femoral pulse wave velocity (PWV) • To assess the change between baseline and 40 weeks in LV mass measured by cardiac magnetic resonance imaging (CMR)

Population

Eligible patients aged 18 years or over, who have a diagnosis of stage 3 CKD (eGFR by 4 variable MDRD equation of 30-59 ml/min/1.73m^2), well controlled blood pressure (office reading of <150/90 mmHg) and are on established (> 6 weeks) treatment with ACEi or ARBs.

Inclusion Criteria	Exclusion Criteria
• Aged over **18 years** • Diagnosis of **stage 3 CKD** (eGFR by 4 variable MDRD of 30-59 ml/min/1.73m^2 on 2 occasions, at least 3 months apart). • **Well controlled blood pressure** (office reading of <150/90 mmHg). • On **established** (>6 weeks) treatment with **ACE inhibitors or ARBs**. • Written **informed consent**.	• Diabetes mellitus • Clinical evidence of hypovolaemia • Recent (<6 months) acute myocardial infarction or other major adverse cardiovascular event • Established diagnosis of left ventricular dysfunction or heart failure • Active malignant disease with a life expectancy of <5 years • Previous hyperkalaemia (K+ ≥6.0 mmol/l without precipitating cause) • Serum K+ ≥5.0 mmol/l at entry • Serum sodium <130 mmol/l at entry • Atrial fibrillation on screening ECG • Use of a thiazide or loop diuretic in the 6 weeks prior to enrolment • Active chronic diarrhoeal illness • Recent active gout (within 3 months) • Episode of acute kidney injury within 3 months • Documented Addison's disease • Current treatment with fludrocortisone, lithium or co-trimoxazole • Office blood pressure <115 mmHg systolic or <50 mmHg diastolic

Trial Updates

First Patient

Congratulations go to UHB for recruiting the first three patients into the trial. We look forward to our other collaborating centres recruiting their first patient.

Database

The database is being developed by BCTU programming team. The data specification has had to go through various iterations to keep pace with the requirements of the trial and the updates to the case report forms. We hope to have the system rolled out to centres within the next few months, at which point sites will be able to register patients and submit completed documentation electronically.

Substantial Amendment

The Trial Management Group, in line with feedback from the DMEC, TSC and various centres has been working on a substantial amendment to the SPIRO-CKD protocol. We hope to submit this amendment during August 2014

BCTU has moved!

As of w/c 21st July BCTU has a new address:

Birmingham Clinical Trials Unit (BCTU)
School of Health & Population Sciences
College of Medical and Dental Sciences
Public Health Building
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Please update your records locally.

A day in the life of a SPIRO-CKD Research Sister

Liz Dwenger is a Senior Cardiology Research Sister and is the SPIRO-CKD Research Sister at University Hospitals Birmingham.

We all know that research nurses come from diverse nursing backgrounds which can only aide in the research process as we begin a new trial. As the Lead Research Nurse, I am responsible for the set-up and running of a clinical trial and this means the administration too! I have been a Cardiology Research Sister for the past 10 years and I am able to use my experience, coupled with the network of research nurses from other specialties within UHB to formulate a strategy in which to initiate such a challenging and worthwhile trial as SPIRO-CKD.

Patient recruitment continues to be a major aspect of any research nurse's role and this trial is no different. I am responsible for finding patients that are both eligible and willing to participate in the trial. So far, this has involved me liaising with fellow colleagues of other specialties, approaching the team, attending meetings and accepting added guidance from them all. I have been able to formulate a sound starting point with the Renal research nursing team here at UHB. I search through the upcoming renal outpatient clinic lists to pre-screen and identify potentially eligible patients that fit the Inclusion/ Exclusion criteria. The clinics vary and may have anywhere from eight to 22 patients in one clinic day, and yes, some clinics will have quite a few suitable patients and another clinic may only present one or two suitable patients! Once I have identified a suitable patient, I ensure that the PI is made aware and reviews the patient's clinical details to confirm eligibility. I will often call the patient, to discuss the trial in addition to sending out the ethically approved Patient Invitation letters with the PIS and Sub-study PIS literature. I also follow up potential participants with a phone call once the PIS letters are sent out in order to allow the patient to discuss any concerns they may have. I then arrange a suitable date and time for the patient to attend their first clinic visit ensuring that all departments and members of the SPIRO-CKD team i.e. the PI, Sub PIs, MRI department and pharmacy are aware that a patient is scheduled in.

It is exciting being at the forefront of research, knowing there are treatments being developed with the potential to make patients' lives and health better. You are also able to build relationships with patients as you see them consistently through their treatment. Every day is different and I really love my job.

As you can see the research nurse is unique, challenging and rewarding. I wish you all the best with your own recruitment techniques!

Something to think about: Florence Nightingale was an avid statistician; a lesser known fact about Britain's best known nurse. She was one of the first to use graphs and tables to present data. Perhaps she would have made an excellent research nurse?





SPIRO-CKD Trial Details

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University of Birmingham

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British Heart Foundation

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The SPIRO-CKD Trial Team

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(Available 9am-5pm, Monday – Friday)

Upcoming Trial Office Closures

SPIRO-CKD Trials Office at BCTU will be closed for the late Summer Bank Holiday **on Monday 25th and Tuesday 26th August**

Thank you for taking the time to read the

SPIRO-CKD Newsletter!