STOP-ACEi Newsletter

Issue 5	March 2015

Full Title: Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease

Short Title: STOP-ACEi

Trial Design:
An investigator-led, multi-centre, open-label, randomised controlled clinical trial.

Trial Aim:
To test the hypothesis that stopping ACEi/ARB treatment, compared with continuing on these treatments, improves or stabilises renal function in patients with progressive stage 4 or 5 chronic kidney disease (CKD).

Population: 410 patients with stage 4 or 5 CKD that have progressive deterioration in renal function (fall in eGFR of >2 mL/min per year over last 24 months) and are currently receiving ACEi/ARB therapy.

Welcome to the fifth issue of the STOP-ACEi Newsletter!
Patient recruitment is picking up and the Investigator Meeting is open to registration.

Have you booked your place for the STOP-ACEi Investigator Meeting?

University of Birmingham Medical School
1st May 2015

Hull and East Yorkshire Hospitals NHS Trust

MRC Medical Research Council

NHS National Institute for Health Research

UNIVERSITY OF BIRMINGHAM

BIRMINGHAM CLINICAL TRIALS UNIT

Message from the Chief Investigator

STOP-ACEi is now truly underway. To have so many sites committed to taking part is a fantastic result, and gives us an excellent opportunity of achieving our target to answer this important question. I believe that with the determination and commitment of all over the next 18 months we will reach our target. I and the other clinical leads for the project will aim to visit centres in the coming months so please contact the STOP-ACEi office if you'd like to arrange a research meeting or seminar.

I have been perusing the literature and the more I read the less sure I am of what to do for patients with advanced CKD on ACEi/ARBs, encouraging me that equipoise remains for this study.

Best wishes,
Prof Sunil Bhandari

STOP-ACEi Investigator Meeting

There are still some places available for the STOP-ACEi Investigator Meeting and we encourage any Principal Investigators, Research Nurses or other staff that will be involved in STOP-ACEi to attend.

Please contact the STOP-ACEi trials office if you would like to attend or have any questions.

Date: Friday 1st May 2015

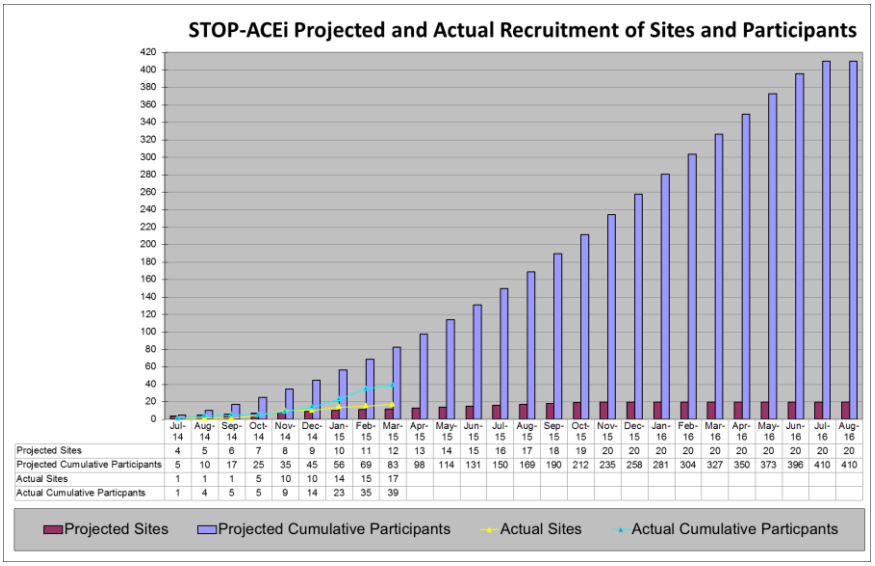
Time: 11am – 3pm

Venue: Centre for Professional Development, University of Birmingham Medical School.

Cost: This meeting is free to attend, but you must register.

Open discussion session: Please contact the STOP-ACEi trials office if you would like to suggest a topic for discussion. We'd like to discuss any issues with the trial or examples of good practice.

Recruitment update – things are looking up!



	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15	Nov-15	Dec-15	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16
Projected Sites	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	20	20	20	20	20	20	20	20	20
Projected Cumulative Participants	5	10	17	25	35	45	56	69	83	98	114	131	150	169	190	212	235	258	281	304	327	350	373	396	410	410
Actual Sites	1	1	1	5	10	10	14	15	17																	
Actual Cumulative Particpants	1	4	5	5	9	14	23	35	39																	

Patient recruitment is still behind target, but has really picked up since the start of the year.

February set a new record of 12 patients recruited in a month.

We know there's a lot of work that goes into identifying and recruiting patients for the trial so we really appreciate all your efforts on this.

Thank you!

Welcome to Jamie Godsall, the new central Data Manager for STOP-ACEi

Jamie Godsall has recently joined the renal trial team at BCTU and has already started chasing missing forms and data. Jamie will be your first point of contact for any queries regarding forms or trial data.

Welcome to new STOP-ACEi centres

Since our last newsletter in December, a whopping 5 new centres have opened to patient recruitment! That's a 50% increase in the number of sites within the last quarter so well done to the following centres for jumping all the regulatory hurdles and opening to recruitment: **St Luke's Hospital** (Bradford), **Kent and Canterbury Hospital**, **King's College Hospital** (London), **Sunderland Royal Hospital** and **The York Hospital**. Three of these centres have already contributed to patient recruitment – well done!

STOP-ACEi Protocol submitted for publication

We are hoping to publish the STOP-ACEi trial protocol in a peer-reviewed journal and it is currently under review at a leading nephrology journal. Publishing protocols for ongoing trials helps to improve the standards and transparency of clinical research and provides an opportunity for the research community to provide feedback. We will circulate the manuscript once it's published.

New summary of evidence for clinicians

A new summary of evidence for clinical staff involved in STOP-ACEi was sent along with this newsletter. This summarises the evidence driving the trial, including a consideration of safety issues for patients with increased cardiovascular risk. Please feel free to share this summary with your colleagues. We hope it will aid understanding and promotion of the trial's aims. If you have any questions or feedback on this, please contact the STOP-ACEi trial office.

Feedback from the funder

We recently submitted our first progress report to the STOP-ACEi funder. They note that we're behind on recruitment, but they agree that we should be able to make up some lost ground and recruit to target within the existing recruitment period. I'm confident we can achieve this if we maintain the momentum seen since the start of the year. They were really pleased that we are ahead of target with opening new sites so thank you for your efforts with trial set-up.

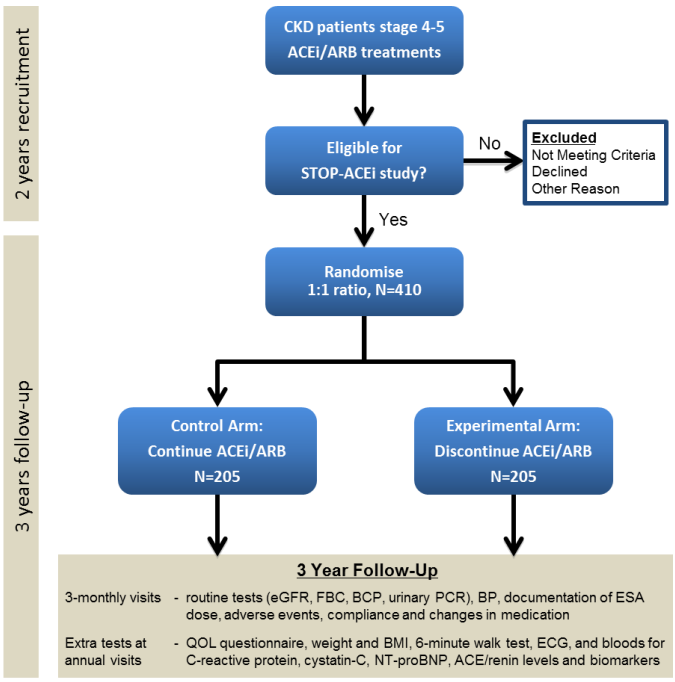
New Guidelines for Completing CRFs

Thank you to all centres for continuing to submit CRFs and responding to queries. As more forms need completing be sure to read the recently issued guidelines around completing CRFs. The guidelines were issued to centres via email on 09 Feb 2015 and should now be safely tucked away in your site file! The guide focuses on common mistakes found in forms completed so far and includes specific guidance around completing the antihypertensive medication tables in Part G of CRF02. This section has caused some confusion but hopefully the guide will clarify what is expected. This guide will be updated as we become aware of any difficulties with form completion. And as always, please get in touch if you have any questions.

New open teleconferences for site staff

We're going to trial a new series of open teleconferences for any staff at participating centres, whether you're in set-up or already recruiting patients into the trial. We hope they will help keep you updated with the latest trial news and progress, and will also give you the opportunity to raise any trial issues, discuss them with your peers and have your questions answered. The first of these will be held on Weds 15th April at 10am. Details to follow.

Study schema



Main Inclusion Criteria

- CKD stage 4 or 5 (eGFR <30mls/minute using the MDRD equation) and not on dialysis therapy;
- Progressive deterioration in renal function (fall in eGFR of >2ml/min/year over previous 24 months, a tool to calculate this will be provided);
- Treatment with either an ACEi or ARB or a combination of both for >6 months with at least 25% of the maximum recommended daily dose on the day of consent;
- Resting blood pressure ≤160/90 mmHg;
- 3 months of specialist renal follow-up at the time of entry into the trial;
- Written, signed informed consent to the trial.

Please see the study protocol for details.

STOP-ACEi trial details:

Sponsor: Hull and East Yorkshire Hospitals NHS Trust Ref: R1578

Funding: The NIHR/MRC Efficacy and Mechanism Evaluation (EME) Programme. Ref: 11/30/07

EudraCT no: 2013-003798-82
ISRCTN no: ISRCTN62869767
REC ref no: 13/YH/0394
IRAS/CSP ref no: 138827

Portfolio adoption: As an NIHR funded study, STOP-ACEi has been adopted onto the NIHR CRN Portfolio.

UK CRN ref no: 15908

The STOP-ACEi study team are always here to help

For further information about the STOP-ACEi trial, please contact us:

STOP-ACEi Chief Investigator:
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Telephone: (0121) 415 9133
Fax: (0121) 415 9135

Randomisation:
Website: www.trials.bham.ac.uk/stopacei
(online randomisation now open)
Telephone: 0800 953 0274
(Available 9am-5pm, Monday – Friday)

Postal address:
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BCTU Easter Closure

Birmingham Clinical Trials Unit, including the telephone randomisation service will be closed from:

17:00, Thursday 2nd April 2015 until
09:00, Thursday 9th April 2015

The online randomisation and data entry service will still be available over the Easter period.