

# STOP-ACEi Newsletter



Issue 2

March 2014

**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

## Welcome to the second issue of the STOP-ACEi Newsletter!

STOP-ACEi has now received REC and MHRA approval and we aim to start patient recruitment in April 2014. We are working towards approval at the lead NHS site.

### 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 over last 12-24 months) and are currently receiving ACEi/ARB therapy.



Hull and East Yorkshire Hospitals   
NHS Trust



  
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## Message from the Chief Investigator

Dear Colleagues,

I am delighted that STOP-ACEi has gained ethics and MHRA approval. This is an important milestone for the trial and we can now focus on getting the study set up in participating sites. We are working hard to finalise the study CRFs and contract templates and aim to have the first patients recruited into STOP-ACEi in April 2014.

There has been an excellent level of interest in the STOP-ACEi trial from investigators, and we have enjoyed engaging and useful discussions at the first meetings of the Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC). Thank you all for your support.

I hope to see you at the STOP-ACEi Launch Meeting in April.

Best wishes,  
Prof Sunil Bhandari



## STOP-ACEi Launch Meeting

**Date:** Thursday 3rd April 2014

**Time:** 10.30am – 2pm

**Venue:** Edgbaston Room, Lucas House, University of Birmingham Conference Park, Edgbaston, Birmingham

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

There are still some places available for the Launch 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.



## STOP-ACEi approved!

STOP-ACEi received a favourable opinion from the Leeds East REC on 29<sup>th</sup> January 2014, a Clinical Trial Authorisation from the MHRA on 12<sup>th</sup> December 2013 and the EME grant started on 1<sup>st</sup> Feb 2014. This is great news and we are now working towards R&D approval at the lead site. Several participating sites have also already started the process for local R&D approval at their own sites – thank you for your hard work.

## Setting up STOP-ACEi at your site

If you will be participating in STOP-ACEi, please complete the Practical Arrangements Form which was sent along with this newsletter. Please contact the STOP-ACEi trials office if you have any questions about study set-up.

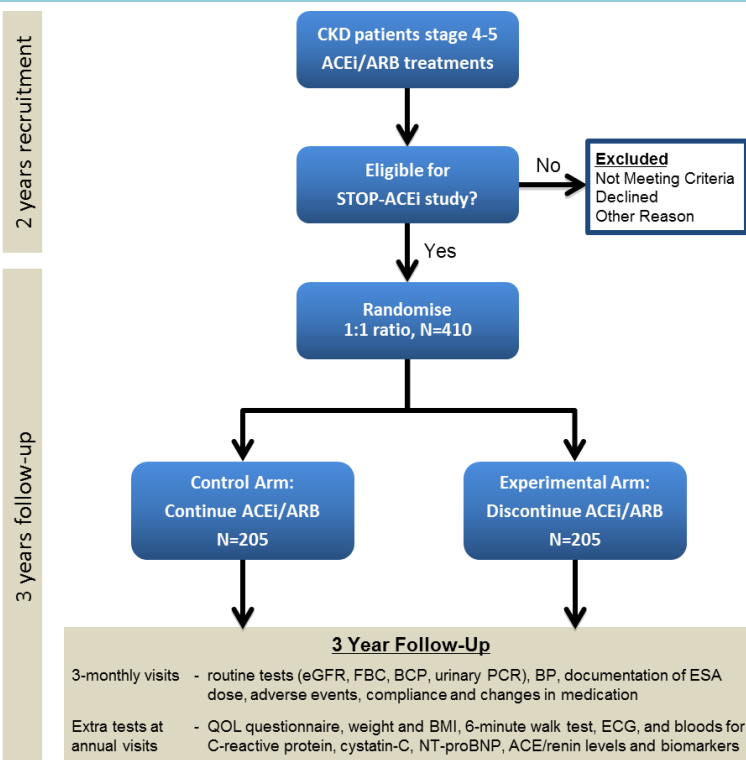
## STOP-ACEi website goes live!

The website for STOP-ACEi is now live. This is a really useful central resource where you can find information for investigators or patients about the trial. You can also download copies of all the REC approved study documents, newsletters and the study CRFs from the website when these are released. Please check it out!

[www.birmingham.ac.uk/STOPACEi](http://www.birmingham.ac.uk/STOPACEi)



## Study schema



## Main Inclusion Criteria

- Aged  $\geq 18$  years (male or female);
- CKD stage 4 or 5 (eGFR  $< 30$ mls/minute using the MDRD equation) and not on dialysis therapy;
- Progressive deterioration in renal function (fall in eGFR of  $> 2$ ml/min/year over previous 12-24 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  $\leq 160/90$  mmHg;
- 3 months of specialist renal follow-up at the time of entry into the trial;
- Written, signed informed consent to the trial.

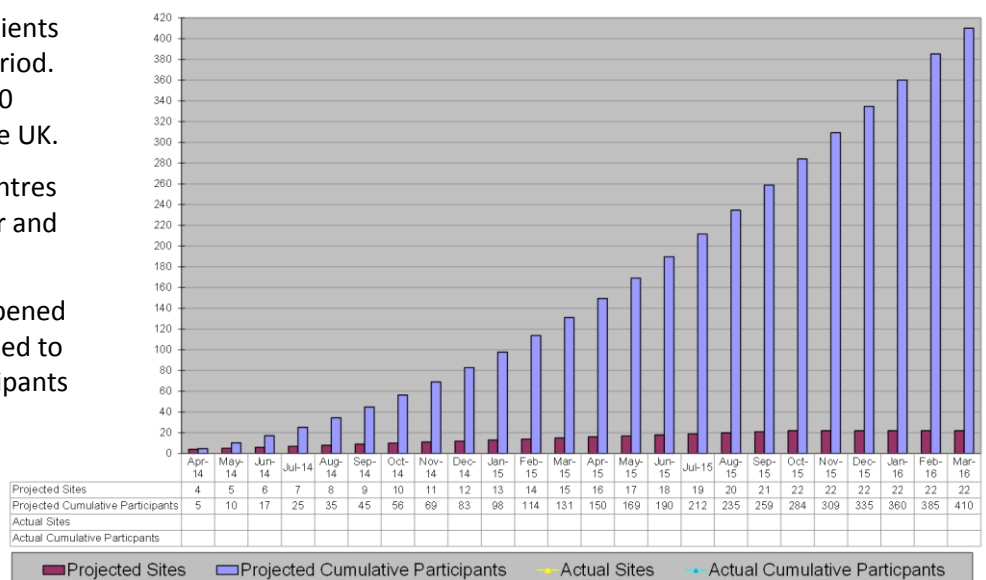
Please see the study protocol for details.

## Projected Recruitment

STOP-ACEi will recruit 410 patients over its 2 year recruitment period. There will be approximately 20 recruitment centres across the UK.

The four main recruitment centres are in Hull, Sheffield, Leicester and Birmingham.

Assuming that 1 new site is opened each month, every site will need to recruit at a rate of 1.15 participants per month for us to reach the recruitment target in time.



## MRC START project

We will be embedding some methodological research into STOP-ACEi as part of the MRC's Systematic Techniques for Assisting Recruitment to Trials (START) project. This will involve randomising some patients to receive the standard Patient Information Sheet and some to receive a Patient Information Sheet with a link to a website to see how this impacts patient recruitment. The website will include information about the trial, a video about the trial and video testimonies from patients that have experience of being involved in research.

For more information about MRC START, please visit their website:

<http://www.population-health.manchester.ac.uk/mrcstart/>



## STOP-ACEi study details:

**Sponsor:** Hull and East Yorkshire NHS Foundation 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 study, please contact us:

### STOP-ACEi Chief Investigator:

Prof Sunil Bhandari, Hull and East Yorkshire Hospitals NHS Trust, [sunil.bhandari@hey.nhs.uk](mailto:sunil.bhandari@hey.nhs.uk)

### STOP-ACEi Trials Coordinator:

Marie Valente, STOP-ACEi Study Office, Birmingham Clinical Trials Unit, [m.valente@bham.ac.uk](mailto:m.valente@bham.ac.uk)

### STOP-ACEi Trials Office:

**Website:** [www.birmingham.ac.uk/stopacei](http://www.birmingham.ac.uk/stopacei)  
**E-mail:** [STOPACEi@trials.bham.ac.uk](mailto:STOPACEi@trials.bham.ac.uk)  
**Telephone:** (0121) 415 9132  
**Fax:** (0121) 415 9135



### Randomisation:

**Website:** [www.trials.bham.ac.uk/stopacei](http://www.trials.bham.ac.uk/stopacei)  
(Website is currently in development)  
**Telephone:** 0800 953 0274  
(Available 9am-5pm, Monday – Friday)

### Postal address:

STOP-ACEi Study Office,  
Birmingham Clinical Trials Unit (BCTU),  
College of Medical and Dental Sciences,  
Robert Aitken Institute,  
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Birmingham, B15 2TT



### Easter and bank holiday closures:

Please note that the STOP-ACEi study office at BCTU will be closed over the Easter break:

from 5pm on Thursday 17<sup>th</sup> April 2014  
until 9am on Thursday 24<sup>th</sup> April 2014

And during the May Bank Holidays:

9am – 5pm on Monday 5<sup>th</sup> May 2014  
9am – 5pm on Monday 26<sup>th</sup> May 2014

Thank you for taking the time to read this STOP-ACEi Newsletter

We look forward to setting up the trial at your site!

