

# STOP-ACEi Newsletter



Issue 9

July 2016

**The STOP-ACEi trial;** A multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease

## Message from the Chief Investigator

Dear all,

I am delighted we have now surpassed 200 patients, a fantastic achievement so far. We now need less than 200 more participants to complete the study; this will represent one of the largest RCTs in this area. If we want to finish recruitment there now needs to be a concerted effort from all sites - recruiting one patient per month from each unit to the end of the year will put the finish line within touching distance. I am confident we can achieve the target and answer an important question for us as clinicians, our patients and help direct future research. The study is being talked about and we have even been on Horizon 2020's radar. I would like to give special mention to the PIs at Kings and Imperial, Martin Ford and Edwina Brown, who have between them recruited 33 patients in less than 13 months. For those about to have a well-earned break, I hope it energises you on your return.

Best wishes,

Prof Sunil Bhandari

## Investigator Meetings – A tale of two cities...

For this year's Investigators' Meetings we are holding 2 regional events – one in London and one in Leeds. We hope this makes travel easier and boosts attendance. Of course, any Northerners prepared to brave the smog are welcome to the London meeting and vice versa. Attendance is free and we will cover reasonable travel expenses, but please register so we can plan catering. I hope you can join us.

### London

Thursday 1<sup>st</sup> September

Institute of Sport, Exercise  
& Health (ISEH)

[Click here to REGISTER](#)



### Leeds

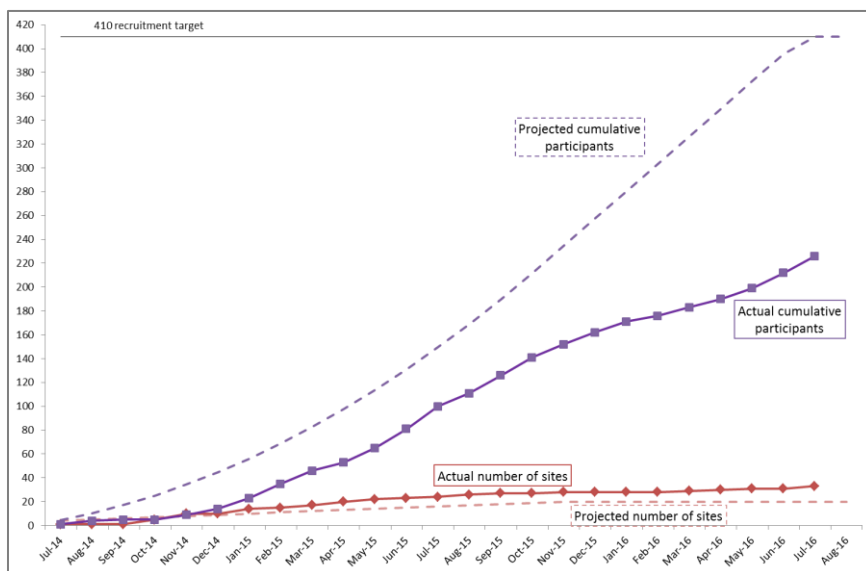
Friday 2<sup>nd</sup> September

Millennium Room at  
The Carriageworks

[Click here to REGISTER](#)



## Recruitment update – Half way there!



Recruitment has really picked up over the last few months. 13 patients were recruited in June – a level not seen since October 2015 – and we’re at 14 for July. This is a great improvement so thank you for your hard work towards this. We are still behind our projections, but are now more than half way to our recruitment target of 410 patients.

## Investigator Meeting

I hope you can join us for one of the STOP-ACEi Investigator Meetings. Please register using the appropriate Eventbrite link:

Leeds – <http://www.eventbrite.com/e/stop-acei-investigator-meeting-leeds-tickets-26777562410>

London – <http://www.eventbrite.com/e/stop-acei-investigator-meeting-london-tickets-26798749782>

Highlights include:

- Update from the Chief Investigator and review of the current evidence base
- Recruitment masterclass with input from research teams
- Put your questions to the Chief Investigator and STOP-ACEi team
- Share your experiences and best practice with other STOP-ACEi collaborators
- Review of trial procedures

Registration is free and we will reimburse reasonable travel expenses, but please register so we can plan for catering. Lunch and refreshments will be provided. Anyone involved in the trial is welcome to attend.

### Leeds



Friday 2<sup>nd</sup> September

Millennium Room at The Carriageworks

### London



Thursday 1<sup>st</sup> September

Institute of Sport, Exercise & Health (ISEH)

## Research Nurse teleconferences

These are mainly aimed at the research nurses, data managers and trial administrators involved in the day-to-day running of the trial, but all are welcome.

Please let us know if you want to raise any items for discussion.

### Dates for your diary:

Wednesday 27<sup>th</sup> July, 3pm

Wednesday 31<sup>st</sup> August, 3pm

Thursday 22<sup>nd</sup> September, 3pm



## Investigator teleconferences

The research nurse teleconferences have been a popular forum for troubleshooting and discussing the trial. We will also start holding regular teleconference meetings for STOP-ACEi Principal Investigators and Co/Sub-Investigators. I hope you can attend.

### Dates for your diary:

Monday 25<sup>th</sup> July, 5pm

Monday 19<sup>th</sup> September, 4pm



## Update on trial extension

We had initially aimed for patient recruitment into STOP-ACEi to be completed by 31 July 2016. This will clearly not be possible anymore and we have applied to the funding body to extend the trial to allow us to recruit the 410 patients needed for the trial. In the meantime, the funding body and ethics committee have confirmed that we should continue with patient recruitment. We will know more about the extension after the funding body meet in October. For now, PLEASE CONTINUE RECRUITING PATIENTS AS NORMAL 😊

## HRA approval for STOP-ACEi



I'm sure you are all aware of the recent changes to the organisation of ethics committees and national research governance. STOP-ACEi gained its initial approvals through the CSP system and these approvals still stand. However, any new sites or future amendments will be processed through the new HRA system. We are currently working on an amendment and plan to add further sites so STOP-ACEi will be brought under the HRA system in due course. Please contact the trial team if you have any questions.

## STOP-ACEi now open in 33 centres, Northern Ireland soon to join

**33 renal centres** across England and Wales are now recruiting into STOP-ACEi. Welcome to the teams at

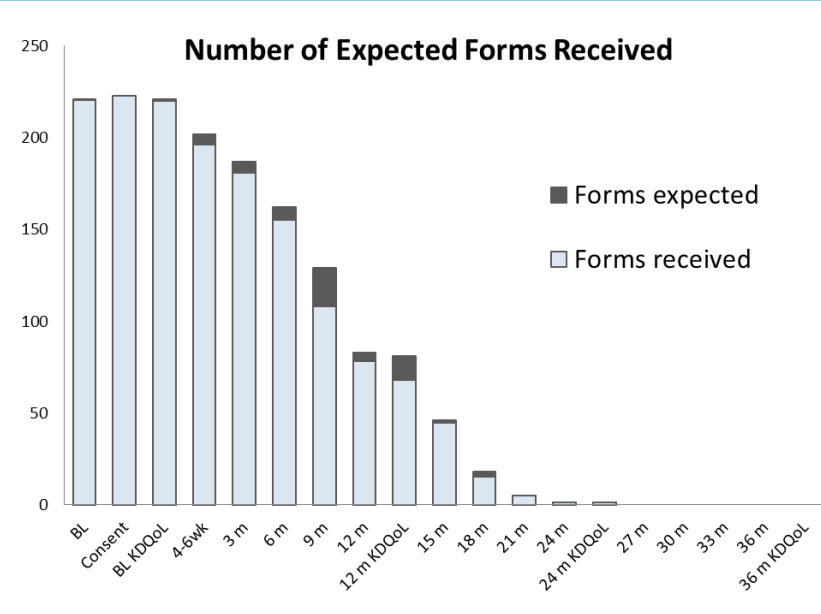
- Dorset County Hospital
- Royal Free Hospital
- Nottingham University Hospitals
- Central Manchester Hospitals
- Calderdale & Huddersfield

who all opened since our last newsletter.

Calderdale & Huddersfield and Dorset have already recruited 2 patients into the trial while Royal Free has 3 already – a great start. We have recently had expressions of interest from some Hospitals in Northern Ireland and are very much looking forward to expanding the STOP-ACEi network. Thank you for your interest in the project.



## CRF Return Rates



Form return rates remain excellent for the trial with **over 95%** of expected forms received.

We have now received **over 1000 follow-up forms** – a heroic effort!

A few of the later forms – for the 9 and 12 month assessments – are outstanding. There has been a big emphasis on patient recruitment lately, but the data is essential for the trial to improve patient care so please remember to keep up with the patient follow-up and data management.

## @NHS.net account for STOP-ACEi

We now have an @NHS.net account set up for STOP-ACEi – [stop.ace@NHS.net](mailto:stop.ace@NHS.net). The normal trial inbox – [stopacei@trials.bham.ac.uk](mailto:stopacei@trials.bham.ac.uk) – will still be the main e-mail account for trial correspondence, but for centres that are phasing out the fax machine, you can now securely send identifiable patient details, such a consent form containing a patient name, to us via this account. Wherever possible, initial SAE reports should still be sent to us by fax. If you need to send an initial SAE report to us via e-mail, you MUST also notify us by telephone. As normal, a message is only secure if sent from another @NHS.net account.

## In the literature...

You might be interested to read this review on ACEi/ARB use in advanced CKD, recently published in NEPHRON: <https://www.karger.com/Article/FullText/447068>

## Trials Units merge in Birmingham

You may have heard that Birmingham Clinical Trials Unit and the Primary Care Clinical Trials Unit, both part of the University of Birmingham, have recently merged. We will still be called Birmingham Clinical Trials Unit, but with additional primary care expertise, staff and studies under one roof. Nothing will change for STOP-ACEi and you probably will not notice any difference, except we have a snazzy new logo to mark the change!

## The STOP-ACEi team are always here to help Please contact us for further information about the STOP-ACEi trial:

### 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 Trial Staff at BCTU:

Marie Valente, Trial Coordinator, [m.valente@bham.ac.uk](mailto:m.valente@bham.ac.uk)  
Jamie Godsall, Data Manager, [j.godsall@bham.ac.uk](mailto:j.godsall@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 9133

**Fax:** (0121) 415 9135

### Randomisation:

**Website:** [www.trials.bham.ac.uk/stopacei](http://www.trials.bham.ac.uk/stopacei)

(online randomisation open 24/7)

**Telephone:** 0800 953 0274

(Available 9am-5pm, Monday – Friday)

**Postal address:** STOP-ACEi Trial Office, Birmingham Clinical Trials Unit (BCTU), School of Health & Population Sciences, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT

## 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



**NHS**  
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Health Research*

Hull and East Yorkshire Hospitals **NHS**  
NHS Trust

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