

# STOP-ACEi Newsletter



Issue 7

September 2015

**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,

The “summer” is now coming to an end; hopefully you will all be refreshed to continue the great work for STOP-ACEi as we are now over 25% of the way to completing recruitment. Although we are behind our recruitment target, the NIHR/MRC are happy for us to continue and I am confident we can accelerate the recruitment in the coming months. I am also reassured that the research question is of great importance to the renal community by the number of additional centres keen to be involved.

As ever I am always available on my mobile 07714986026 for any queries or problems and am happy to visit centres.

Best wishes,  
Prof Sunil Bhandari



## MRC START sub study now live

At long last, the START project has now been fully implemented after some initial delays. All open centres have now received their updated documents. Thank you for your patience.

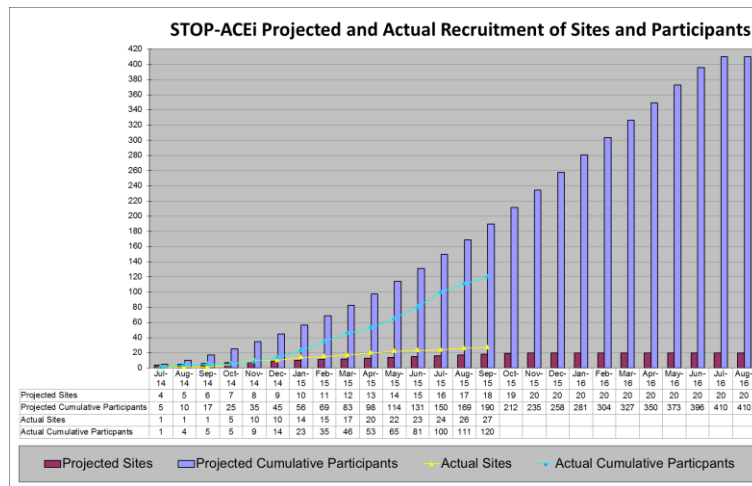
As part of the START sub-study, some centres have had changes to their PIS and invitation letter to add a link to a website that gives potential participants information about the trial, including videos from the Chief Investigator, a research nurse and patient representative.

We hope to show that this sort of patient information website helps with patient recruitment so that they can be developed for more NIHR and MRC-funded studies in the future.



Videos on the START website give information about the trial to potential participants

## Recruitment update – Over 100 patients recruited!



There are now 120 patients recruited into STOP-ACEi

We continue to track the projected recruitment rate at around 3 months behind target.

With the holiday season, there was a slight dip in August. We hope you are reinvigorated to boost recruitment over the coming months!

Please continue with your efforts identifying new patients.

## Top recruitment tips from King's

King's College Hospital London is second only to Hull in patient recruitment and holds the record for most patients recruited in one month. We've spoken to Dani, the study coordinator at King's for some top tips for recruitment.

**Regular screening from renal database:** Our Renalware database helps a great deal with pre-screening and identifying potential patients. I look at the general nephrology and low clearance clinic lists at least 2 weeks in advance and check against the eligibility criteria using the database.

**Regular meeting with the PI:** I meet with the PI once a week to discuss potential subjects and he decides whether to send out the PIS based on their full background and other medical history.

**Organisation:** I email the PI every week with a reminder of the potential patients so he can speak to them more about the study during their appointment.

**Teamwork:** Overall, I think having a very hands-on PI, a supportive research matron and a good team have all helped us to achieve and put us in the place we are now.

**Problems overcome:** As I was handling other studies and the PI has other clinical duties it was difficult communicating only via email. Having to commit to a specific time of the week to discuss the study and the potential subjects helped us overcome this. Time (PI and Nurse) was a bit of a hurdle during the start of the study. Additional time from the data manager / research assistant also provided me the hand that I needed, especially during pre-screening and performing study procedures.

## Research Nurse teleconferences

Due to their popularity, we will now hold a research nurse teleconference every month.

### Dates for your diary:

Thursday 15<sup>th</sup> October, 3pm

Monday 9<sup>th</sup> November, 3pm

Tuesday 8<sup>th</sup> December, 3pm

Wednesday 20<sup>th</sup> January, 3pm



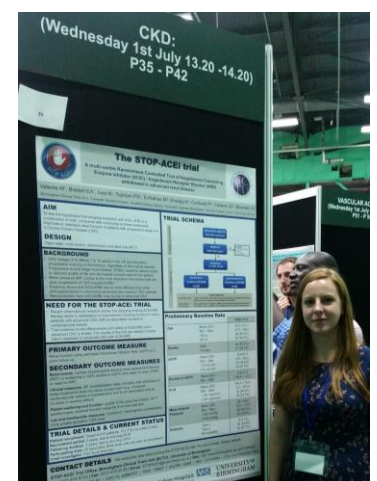
These are mainly aimed at the research nurses, data managers and trial administrators involved in the day-to-day running of the trial, but all are welcome.

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

## STOP-ACEi at BRS 2015

The Chief Investigator and trial coordinator for STOP-ACEi were at the British Renal Society meeting in Leeds this summer to promote the trial.

It is clear from our conversations that our research question is important and relevant for the renal community.



## Six more centres open to patient recruitment

Six new centres have opened to patient recruitment since our last newsletter in June 2015. A warm welcome to the teams at **Birmingham Heartlands Hospital, Doncaster Royal Infirmary, Gloucestershire Royal, Sheffield Northern General, Royal Liverpool** and **James Cook Hospital, Middlesbrough**. Thank you for all your hard work with trial set-up.

## Main Inclusion criteria

Please see the study protocol for details.

- 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, calculated using the STOP-ACEi eGFR decline tool);
- Resting blood pressure ≤160/90 mmHg;
- Treatment with an ACEi, ARB or a combination of both for >6 months, with at least 25% of the maximum recommended daily dose on the day of consent;
- 3 months of specialist renal follow-up at the time of entry into the trial;
- Written, signed informed consent to the trial.

## 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

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