

# STOP-ACEi Newsletter



Issue 6

June 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

It was great to meet some of you at the recent Investigator Meeting. It was also reassuring to hear of the importance of this study. Indeed more centres are keen to get involved so there is much cause to be optimistic. As with all studies recruitment remains challenging, we are currently 15% of the way and if each centre could make a concerted effort to recruit 1 patient a month until the end of the study we will get there and hopefully change clinical practice. I would be happy to visit units to help spread the message to all.

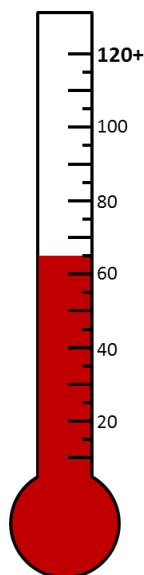
Best wishes,  
Prof Sunil Bhandari

## Recruitment challenge!

Can we reach 120 patients by the end of July?

If we recruit **3 patients at each centre over the next 2 months before the summer break approaches**, we can reach this initial goal!

There has been a fantastic level of interest from participating sites. We need to translate this enthusiasm into patient numbers to achieve our recruitment target within the funded time-frame and find the answer to this important clinical question.



## Feedback from the Investigator Meeting

The STOP-ACEi investigator meeting took place at University of Birmingham on 1<sup>st</sup> May 2015. Delegates attended from 14 participating centres and feedback has been really good.

Thank you all for your input in the discussion and question sessions. Many of you said you appreciated the opportunity to network and discuss the trial with other research nurses and investigators.

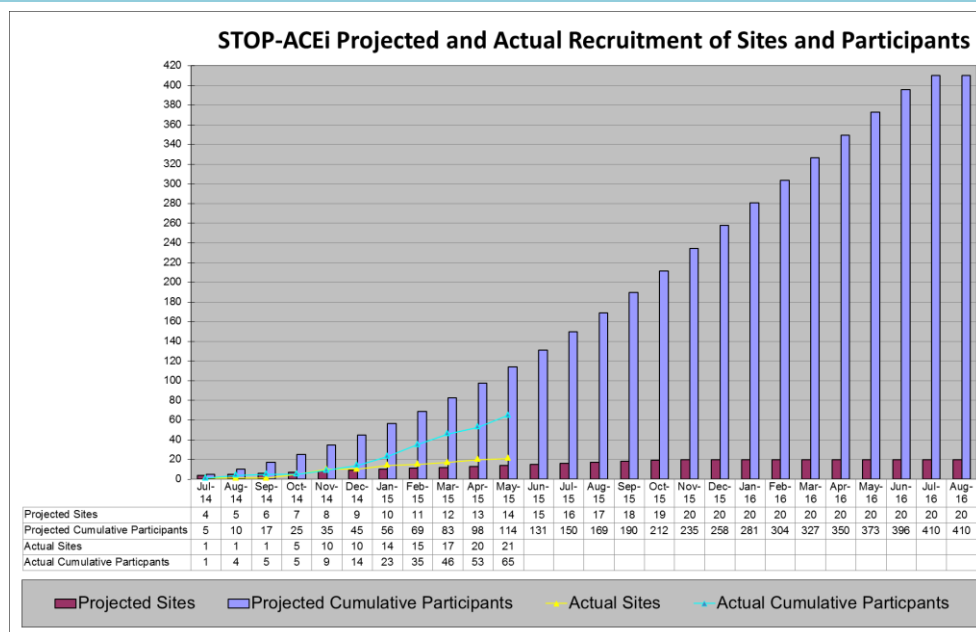
*"Well worth attending, thank you"*

*"Going over all the background evidence etc. will greatly help when discussing the study with patients"*

*"Practical information at the correct level"*

*"The whole meeting was well organised and informative. Plenty of time for discussion and Q&A"*

## Recruitment update



After a slow April, patient recruitment picked up slightly in May, but we remain behind target and the monthly rate of recruitment is much lower than expected.

Please continue with your efforts identifying new patients.

## Six new centres open to patient recruitment

The STOP-ACEi community continues to grow as **six new centres** have opened to patient recruitment since our last newsletter in March 2015. A warm welcome to the teams at **Colchester General Hospital, Leicester General Hospital, Morrision Hospital (Swansea), Royal Preston Hospital, Charing Cross Hospital (London) and New Cross Hospital (Wolverhampton)**. Thank you for all your hard work with trial set-up.



## Major update to the STOP-ACEi online system

The new version of the online randomisation and data entry system for STOP-ACEi was released on 27<sup>th</sup> May 2015.

Please bear with us as we enter the backlog of data for paper forms already received. Please contact us if you have any questions.

Access the system at:

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

### New and updated features:

- All forms now available
- Online version of the eGFR decline calculator with built in date check
- E-mail reminders for upcoming assessments and overdue data
- Ability to edit contact list for automatic e-mails
- Ability to transfer forms between users
- Addition of a 'Monitor' role

## Next open teleconference for site staff

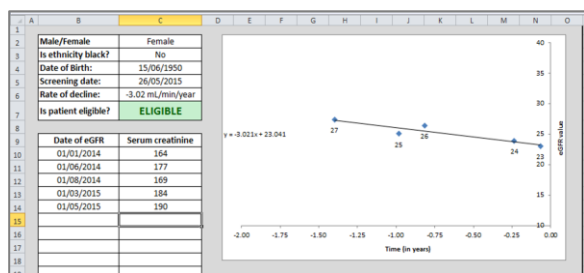


The next teleconference will take place on **Thursday 18<sup>th</sup> June 2015 at 10 am**. Everyone is welcome to attend, but it's mainly aimed at the research nurses, data managers and trial administrators involved in the day-to-day running of the trial. Please let us know if you want to raise any items for discussion.

## Update on Substantial Amendment 04 for the MRC-START sub-study

This amendment cannot be implemented until the multimedia intervention website has been finalised. Unfortunately there were some problems with the first draft of this which are currently being corrected. An external web development company is currently working on this. Please accept our apologies for the delay. When the website is ready we will provide the correct version of the updated documents for your site. This amendment was submitted for REC review on 12 Feb 2015 and gained a favourable opinion on 19 Mar 2015.

## Improvements to the eGFR decline calculator



A new version of the STOP-ACEi eGFR decline calculator was sent out on 13th May 2015. The updated version can now automatically update the graph as you enter new creatinine readings.

Use the calculator to check if a patient has the required 2mL/min/year decline in eGFR to be eligible for STOP-ACEi.

## Your questions answered

- Q.** A STOP-ACEi patient has had a short-term period of dialysis, how do I record this?
- A.** Where the form asks “Has the participant started renal replacement therapy?” this refers to long term/permanent treatment so you should still answer ‘no’. Please record any related adverse events (e.g. AKI) or hospital admissions in the AE and clinical visits sections of the CRF as normal. If there has been an SAE, you should also report this by fax using an SAE form within 24 hours of being notified of the event.
- Q.** A potential patient has a non-renal immune disease, are they eligible for STOP-ACEi?
- A.** Patients with immune mediated renal disease may be excluded from STOP-ACEi if they require disease-specific treatment (e.g. active course or induction phase of treatment) at the time of trial entry, but patients with non-renal immune diseases, such as asthma, can be included.

## 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 now open)

**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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