

STOP-ACEi Newsletter

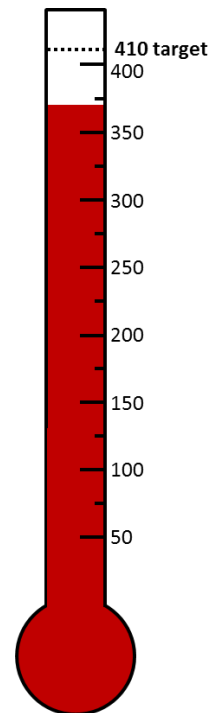
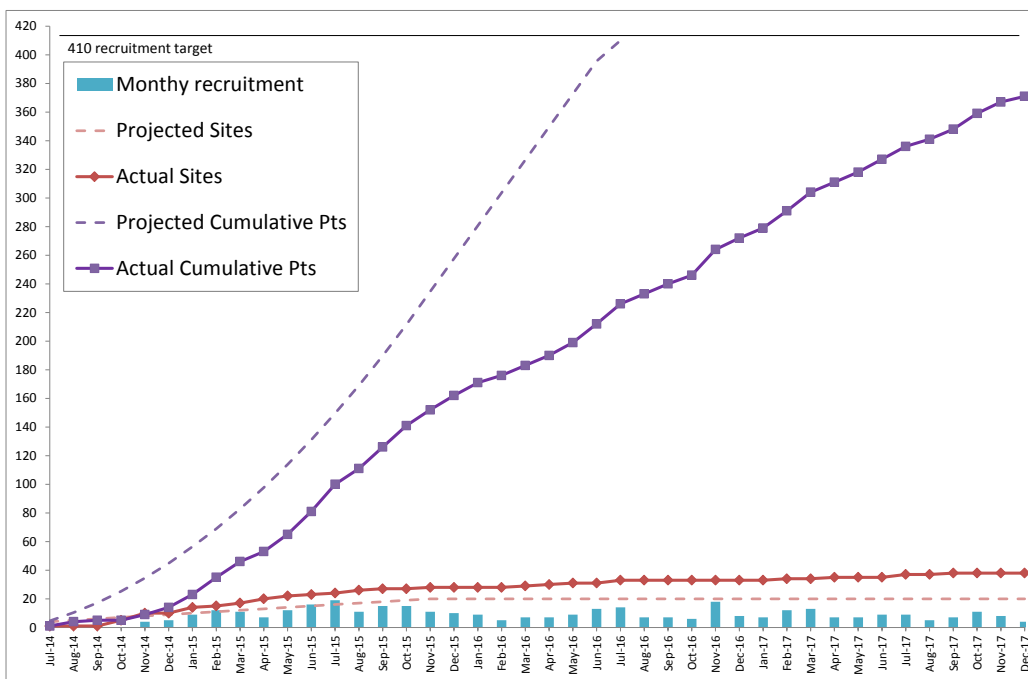


Issue 13

Dec 2017

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

Recruitment update – thank you for your continued efforts!



There are now 371 participants enrolled in the trial. That is 90% of our target! Just 39 more participants are needed to complete recruitment. The finish line is in sight.

We'd like to extend a huge thank you to all the research teams for their efforts towards finding and enrolling new participants into the trial.



Message from the Chief Investigator

Dear all,

Debate on the STOP-ACEi trial continues to gather momentum. I hope as we approach the festive season all the renal researchers involved, who have made a fantastic effort to reach 371 patients in the trial – the largest of its kind – can muster up a final push so, I get my wish from Santa and I can maybe bring some New Year's cheer to you all. This trial is a potential game changer and I believe one which will change clinical practice in the future. We owe it to those 371 patients who have committed their time and belief in us to complete this study and also verify to the NIHR that the renal community can deliver on important clinical trials.

Wishing you all a very happy Christmas and restful New Year.

Best wishes,

Prof Sunil Bhandari



STOP-ACEi database changes

The STOP-ACEi database has recently been updated. One change you will notice is a new form has been added to the assessments list at the baseline and annual time-points called 'Sample Info'. The 'Sample Info' form has been created to help us keep track of samples that have been collected at sites and with arranging sample collections. The form is pre-populated with the sample information you already provide in the follow-up CRF. You do not need to do anything with the 'Sample Info' forms, they are there to help us and for your information only.

As part of the update, BCTU staff are now completely locked out of making data changes on behalf of sites. We have not been making changes for some time anyway, however this change has now been formalised. We can still view the forms, but cannot make any changes to the data in the follow-up forms.

Christmas closure and SAE reporting over Christmas

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

14:00, Friday 22nd December 2017 until

09:00, Thursday 4th January 2018

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

SAE reporting continues over Christmas.

Please e-mail any new SAE reports directly to the Chief Investigator and CC in the trial's @NHS.net account.

Sunil.Bhandari@hey.nhs.uk

stop.ace@nhs.net

These will be monitored over the Christmas break.

STOP-ACEi recruitment continues

Recruitment to STOP-ACEi continues as normal. The recruitment end date has now been updated to the end of April 2018 on the CPMS system and the NIHR have urged us to complete patient recruitment as soon as possible.



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:

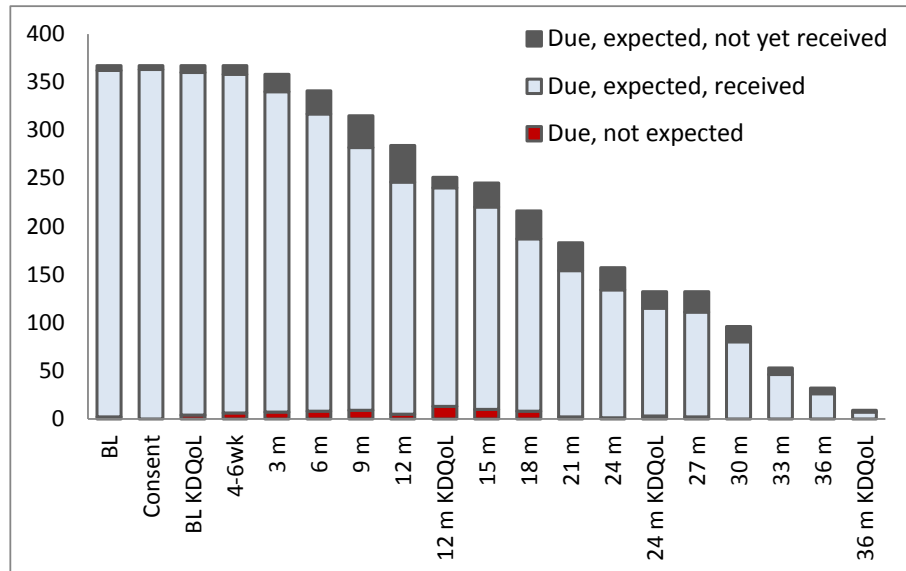
Tuesday 30 January 2018, 3pm

Monday 26 February 2018, 2pm

Thursday 29 March 2018, 2pm



Form returns



Over 90% of the expected forms have been returned for STOP-ACEi so far – that’s 3868 forms!

The returns for QoL questionnaires have improved since Jamie’s latest appeal. Thanks for getting these back to us.

Remember to let us know if a patient has missed any follow-up visits.



The STOP-ACEi team are always here to help

Please contact us for further information about the STOP-ACEi trial:

STOP-ACEi Chief Investigator:

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STOP-ACEi Trial Staff at BCTU:

Marie Valente, Trial Coordinator, m.valente@bham.ac.uk
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E-mail: STOPACEi@trials.bham.ac.uk

Telephone: (0121) 415 9133

Fax: (0121) 415 9135



Randomisation:

Website: 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), 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

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

UK CRN ref no: 15908

IRAS/CSP ref no: 138827

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