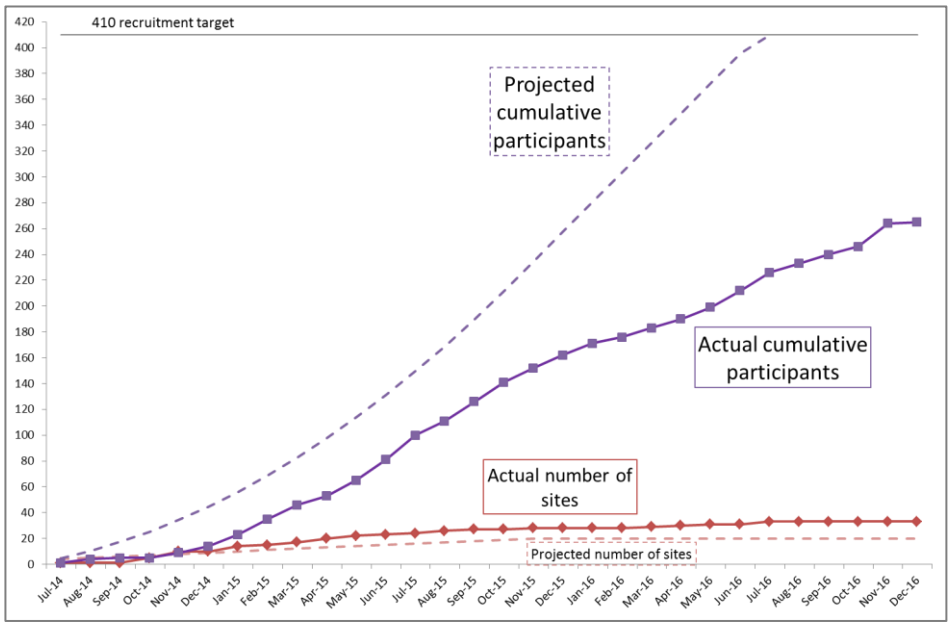
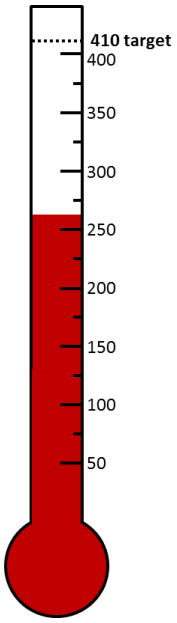
STOP-ACEi Newsletter

Issue 10 December 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

Recruitment update





STOP-ACEi now has 267 participants.

That is 65% of our required target.

5 more patients in each centre will complete recruitment

There was a real surge in recruitment in November with 18 patients recruited – wow! Thank you for your hard work finding new participants. Special mention goes to Dr Mark Uniacke, Joan Buckland and the team at Queen Alexandra Hospital in Portsmouth who recruited a record-equalling 4 new participants in November. Thank you.

Christmas closure

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

14:00, Thursday 22nd December 2016 until

09:00, Wednesday 4th January 2017

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

SAE reporting continues over Christmas as normal.

Please continue to fax any new SAE reports to 0121 415 9135.

The fax will be monitored over the Christmas break.

Message from the Chief Investigator

Dear all,

The STOP ACEI Trial continues towards our target. We have now reached 267 participants, the largest study in this field. The NIHR remain supportive and have categorically stated they want the study to be completed. I thank everyone for their continued support and emails to that effect, including from Donal on behalf of the Renal Association.

At the recent British Heart failure Society Meeting I was encouraged by the lack of good data in this challenging area and that the question of what to with ACEi/ARB remains highly clinically relevant. No one can really be sure of what the right answer is, thus giving continued equipoise for the trial. There remains a split on what is the best thing to do. Indeed it was suggested that those who are progressing in renal dysfunction may benefit from continued ACEi/ARB treatment. This reminds me of several studies where "intuition" was eventually proved wrong with an RCT.

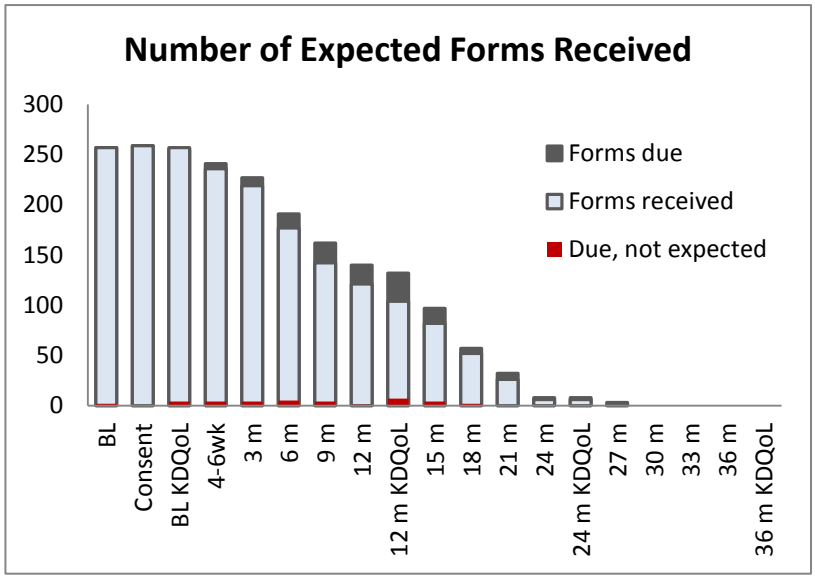
I am confident that the NIHR will provide additional funding to allow us to recruit the remaining 145 patients over the next year. This means only 5 more participants from each site. So next time you see a patient "STOP" and think, do I really know the best plan or should I put them in a trial?

Once again many thanks for the ongoing great support.

Best wishes,

Prof Sunil Bhandari

Form return rates look great, but remember the quality of life questionnaires



A trial needs good quality data to improve clinical practice. Thank you for all your hard work completing and returning the forms.

Overall we have received 90% of due forms, which is fantastic.

But at the moment, we only have 72% of the expected KDQoL questionnaires for the 12 month visit.

Without the questionnaires, we cannot know the impact of the intervention on patient wellbeing and renal symptoms. It is the only information we get directly from the patient, so please remember to ask the patient to complete the quality of life form at annual visits.

Extension for the STOP-ACEi trial – Recruitment continues as normal

In March 2016 we submitted a request to the funding board to extend the project to allow recruitment to continue and reach our target of 410 patients. They have now confirmed they want the study to continue to completion. We are due to meet them in December to discuss plans for the project. We will let you know about any changes for the project and the new recruitment end date as soon as we can. **In the meantime, recruitment continues as normal**.

Investigator Teleconferences

The next teleconference for participating Principal- and Co-Investigators will be on:

- Tuesday 10th January 2017, 5pm

Nb. The teleconference planned for 13 Dec 2016 is cancelled.

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:

Thursday 19th January 2017, 3pm

Wednesday 22nd February 2017, 2pm

Monday 27th March 2017, 3pm

Staff changes at your centre?

Please remember to let us know. For all staff completing delegated duties for STOP-ACEi, we need a copy of:

- CV signed within the last 12 months
- GCP certificate, valid according to local policy
- Signed off delegation log

Copies should also be filed in section 4 of your site file.

Access to the trial randomisation and data entry system is granted based on the delegation log.

Trial Samples – a few reminders

Remember to collect the extra trial samples at:

- baseline visit
- 12 month visit
- 24 month visit
- 36 month visit

The following samples should be taken at every annual sampling visit:

- 2 x aliquots of serum
- 2 x aliquots of EDTA plasma
- 3 x aliquots of serum for biomarkers*
- 3 x aliquots of urine for biomarkers*
- Total = 10 tubes

*The biomarker samples are optional, depending on participant consent.

Make a note of any problems with sample collection on the CRF for that visit.

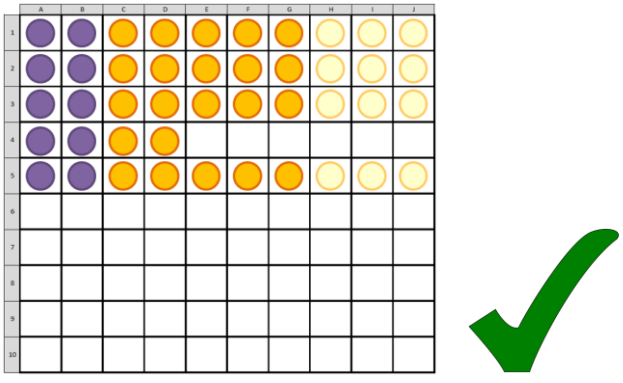
For full details, check the STOP-ACEi guide for sample preparation. There is a copy in section 8 of your STOP-ACEi site file or available on the trial website:

www.birmingham.ac.uk/stopacei/docs

Packing samples for collection:

- Always use the provided labels, tubes and sample storage boxes
- Use the correct colour-coded caps for the type of sample
  - Yellow = serum
  - Purple = EDTA plasma
  - Clear = urine
- Put samples for one visit along 1 row in the sample storage box
- Update your freezer log electronically whenever you add new samples to the freezer

This is what your sample box should look like for 5 sample visits, with 1 patient not giving consent for the additional biomarker samples:



Dialysis and transplant - is it an SAE?

An adverse event that requires hospitalisation is usually reported as an SAE, but there are a couple of exceptions for STOP-ACEi. Events NOT considered to be SAEs (see Trial Protocol, section 10.3.1) are hospitalisations for:

- Routine treatment or monitoring of the studied indication, not associated with any deterioration in condition
- Treatment, which was elective or pre-planned, for a pre-existing condition that is unrelated to the indication under study, and has not worsened

STOP-ACEi participants have advanced progressive CKD, so a planned admission for transplant or elective fistula formation can usually be considered part of routine treatment of the studied indication, i.e. not an SAE.

Remember that complications during the admission (e.g. a fistula site infection) or an acute admission that requires unplanned dialysis can still class as an SAE. Regardless of whether the event is an SAE, you must always report the participant commencing dialysis/having a transplant in the RRT section of the next follow-up form, but only an SAE requires the full details in the SAE report.

If in doubt, it is always better to report. Please call us if you have questions.

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

STOP-ACEi Trial Staff at BCTU:

Marie Valente, Trial Coordinator, m.valente@bham.ac.uk

Jamie Godsall, Data Manager, j.godsall@bham.ac.uk

STOP-ACEi Trials Office:

Website: www.birmingham.ac.uk/stopacei

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

BCTU Christmas Closure

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

14:00, Thursday 22nd December 2016 until

09:00, Wednesday 4th January 2017

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

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

Hull and East Yorkshire Hospitals NHS Trust

MRC Medical Research Council

NHS National Institute for Health Research

University of Birmingham | BCTU Birmingham Clinical Trials Unit