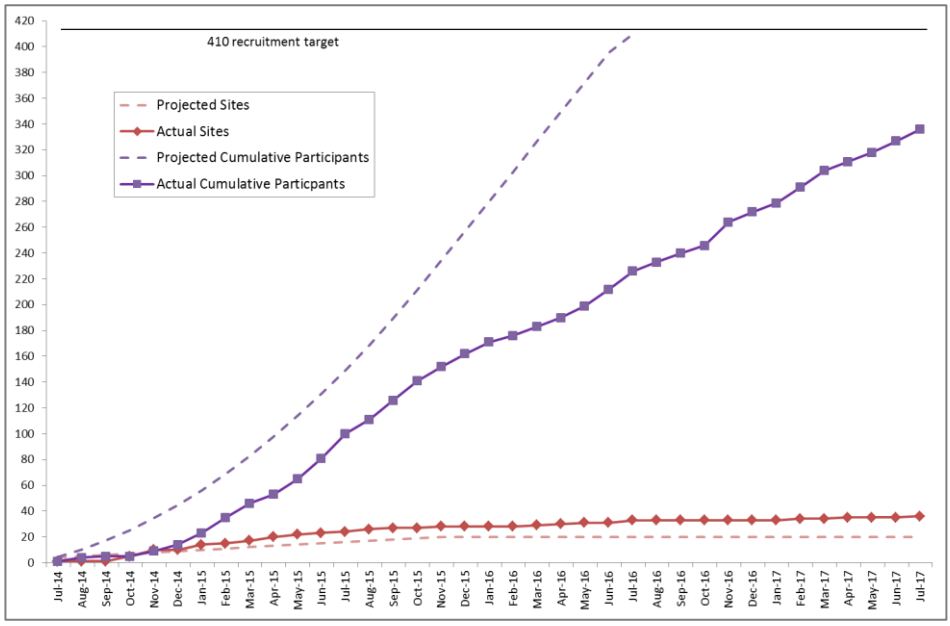
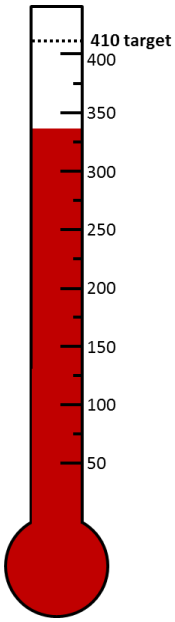
STOP-ACEi Newsletter

Issue 12 | Jul 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





STOP-ACEi now has 336 participants.

That is 82% of our required target.

74 more patients are needed to complete recruitment

STOP-ACEi Investigator Meeting 2017 – help us choose the best date

This year, the Investigator Meeting will be held at the Charles Street Building, Sheffield Hallam University.

We'd like to have as many of you there as possible. The meeting will be on either 12th or 14th September. Please let us know which dates you can make by voting at the following link:

https://doodle.com/poll/htkwknms9xbh7vsk

Or alternatively, e-mail the STOP-ACEi inbox with your preference at STOPACEi@trials.bham.ac.uk.

We will refund reasonable travel costs for all attendees. We hope you can make it.

STOP-ACEi Investigator Meeting 2017 will be held at Charles Street Building, Sheffield Hallam University

Message from the Chief Investigator

Dear all,

I'd like to thank all the Investigators and research teams participating in the STOP-ACEi trial for all the hard work that has gone into the project so far. A huge collective effort has gone into recruiting the 336 participants we have in the trial. The NIHR are keeping a close eye on our progress, and when I meet with them again in December, I hope I can show them that we have completed recruitment. We need just 74 more patients to reach that goal, that's just 2 more from each open centre. I urge all teams to look again at your clinic lists and patient databases, and make a final push to complete recruitment. I'm delighted that several new centres in Wales and Northern Ireland have joined recently to help us towards this goal.

What to do with RAAS blockers in advanced CKD has been a hot topic in recent meetings and literature. With a joint push, we can help resolve this issue and improve patient care.

I look forward to seeing many of you at the Investigator Meeting in September.

Best wishes,

Prof Sunil Bhandari

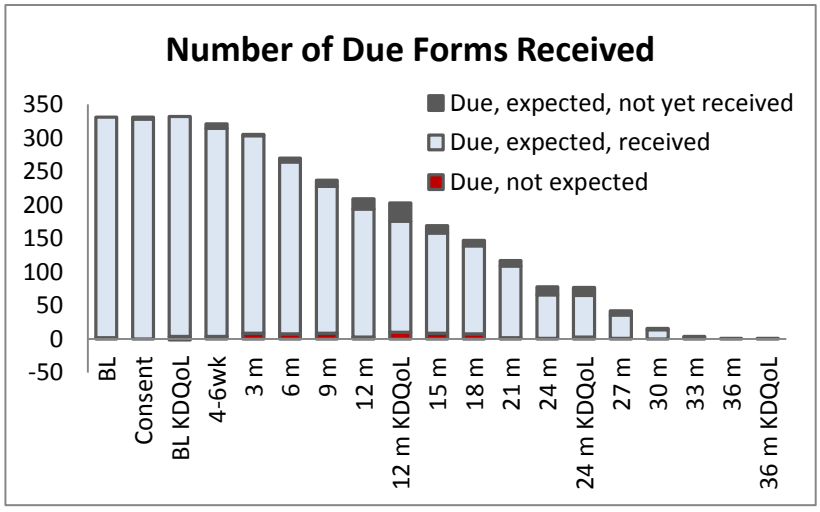
STOP-ACEi at major renal meetings and in the recent literature

STOP-ACEi was a topic of discussion at the 54th Congress of the ERA-EDTA in Madrid and at UK Kidney Week 2017 in Liverpool this June. It is clear from the discussions that there is still a lot of uncertainty as to what to do with ACEi/ARB treatment for patients in the advanced stages of CKD.

A recent systematic review and meta-analysis of ACEi/ARB use in advanced CKD and diabetes concluded that "the question of whether to prescribe or withhold RAAS-blocking agents in patients with DM and CKD stages 3–5 cannot be answered with confidence based on the available evidence". The authors highlighted STOP-ACEi, saying "fortunately, results of an ongoing trial may be available in the future…The results of this trial will show whether discontinuation of ACEIs/ARBs can improve or stabilize renal function in patients with advanced progressive CKD". *Nephrol Dial Transplant (2017) 1–11. doi: 10.1093/ndt/gfx072*

This reminds us that all STOP-ACEi Investigators, research teams and patients are contributing to a major study, which will help address an important clinical question and guide future care for people with advanced CKD.

Form return rates – remember the Quality of Life questionnaires



Around 95% of the expected forms have been returned for STOP-ACEi so far, which is great.

However, returns for QoL questionnaires have not been as good. Around 20% of the questionnaires due from the 12 month visit have not yet been returned, in many cases, because they were not completed. Please remember to ask the patient to complete the questionnaires at each annual assessment.

Updated safety information for ACE inhibitors

The drug safety information for Lisinopril has recently been updated. There are no changes to the STOP-ACEi trial, but we'd like to make you aware of the changes to the sections on 'special warnings and precautions for use' and 'Interaction with other medicinal products and other forms of interaction'.

- "Patients taking concomitant mTOR inhibitors (e.g. sirolimus, everolimus, temsirolimus) therapy may be at increased risk for angioedema (e.g. swelling of the airways or tongue, with or without respiratory impairment)"
- "Patients at risk for the development of hyperkalaemia include those with renal insufficiency, diabetes mellitus, or those using concomitant potassium-sparing diuretics, potassium supplements or potassium-containing salt substitutes, or those patients taking other drugs associated with increases in serum potassium (e.g. heparin, co-trimoxazole also known as trimethoprim/sulfamethoxazole). If concomitant use of the above-mentioned agents is deemed appropriate, regular monitoring of serum potassium is recommended"

The STOP-ACEi Protocol states, "Throughout the trial, investigators may prescribe any concomitant medications or treatments deemed necessary to provide adequate supportive care to participants", and monitoring of potassium is routine for patients with advanced CKD. STOP-ACEi investigators should continue to employ best prescribing practice, which takes the patient's clinical status and latest guidelines into consideration.

The latest prescribing information is found at the electronic Medicines Compendium: www.medicines.org.uk

Ongoing recruitment for STOP-ACEi

Recruitment to STOP-ACEi continues as normal. The recruitment end date has been updated to the end of 2017 on the CPMS system and the NIHR have urged us to complete patient recruitment as soon as possible.

The NIHR will next review the project in December 2017 and we hope to have completed recruitment at this point. There is no guarantee they will allow any additional time for recruitment.

SUSAR notification

A SUSAR notification was sent out on 15 Jun 2017. If you haven't already done so, please send us evidence of PI review of this event. There is no change to the risk/benefit balance for the trial in light of this event and no changes to the trial are required.

All investigators are reminded to follow NICE guidance for blood pressure targets for all patients in the trial, but avoiding use of ACEi/ARBs in the STOP arm wherever possible.

MHRA inspection at STOP-ACEi Sponsor

The trial Sponsor, Hull and East Yorkshire Hospitals NHS Trust, has been selected for MHRA Statutory GCP Inspection. We do not yet know if STOP-ACEi will be selected as a focus of the inspection, but we will keep you updated if we hear any further news. You may want to take this as an opportunity to check your documents are all up to date. Please get in touch if you need any documents or have questions.

- Check your ISF is up to date
- Check your delegation log is up to date and accurate
- Check patient records are complete and up to date

MHRA
Regulating Medicines and Medical Devices

New sites for STOP-ACEi

We'd like to welcome the teams that have opened to recruitment since the start of the year:

- Glan Clwyd Hospital, Betsi Cadwaladr UHB
- Altnagelvin Hospital, Western HSCT
- Daisy Hill Hospital, Southern HSCT
- Antrim Area Hospital, Northern HSCT

There is one more site due to open for STOP-ACEi, Barking Havering Redbridge NHS Trust, which will bring the total count to 38 recruiting centres for STOP-ACEi.

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 17 August 2017, 2pm
Thursday 12 October 2017, 2pm

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

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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