

STOP-ACEi Newsletter

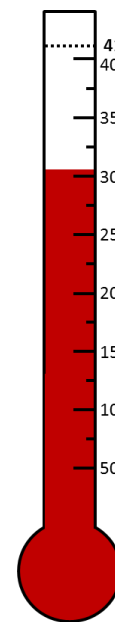
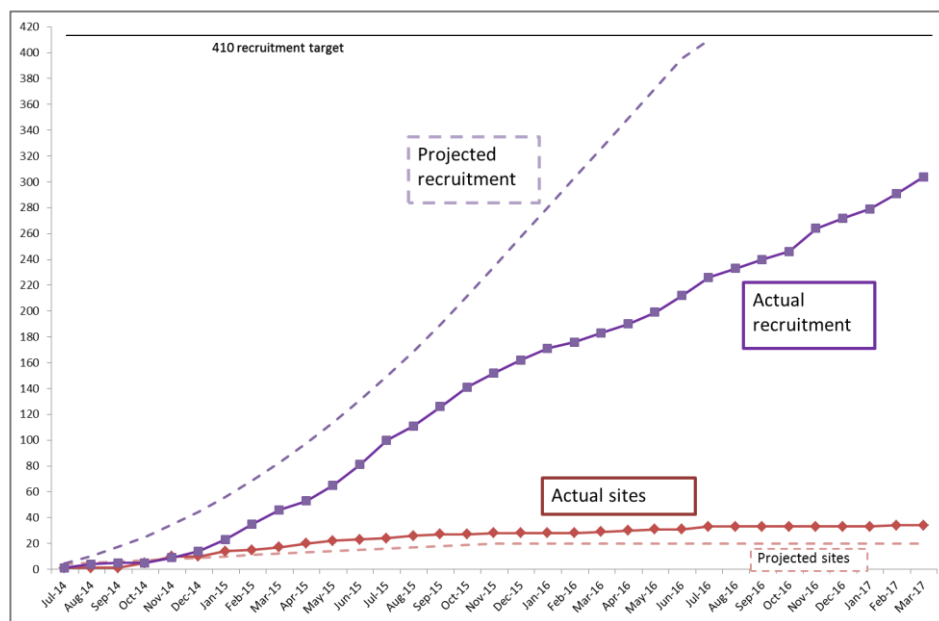


Issue 11

April 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 305
participants.

That is 75%
of our
required
target.

3 more
patients in
each centre
will complete
recruitment

The recruitment rate for the start of 2017 has been fantastic with 12 and 13 patients recruited in February and March, respectively. Thank you for your continued efforts. Please keep up the search.

Easter closure

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

17:00, Thursday 13th April 2017 until

09:00, Thursday 20th April 2017



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

SAE reporting continues over Easter as normal.

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



Message from the Chief Investigator

Dear all,

I am delighted to report we have now surpassed 300 patients, a fantastic achievement so far and almost at the point where we can count down from 100 patients left to recruit. This has not happened without a huge amount of hard work and commitment from many people from the 34 centres involved and I thank all of them. I would urge everyone to try and recruit as many patients into the trial between now and July to avoid Summer and maybe Easter dips. I remain confident we can achieve the target by the end of the year and answer an important question, and potentially reduce dialysis requirement. I would like to thank especially those centres that have reached, and in several cases surpassed, their initial target recruitment and hope they will continue to recruit.

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

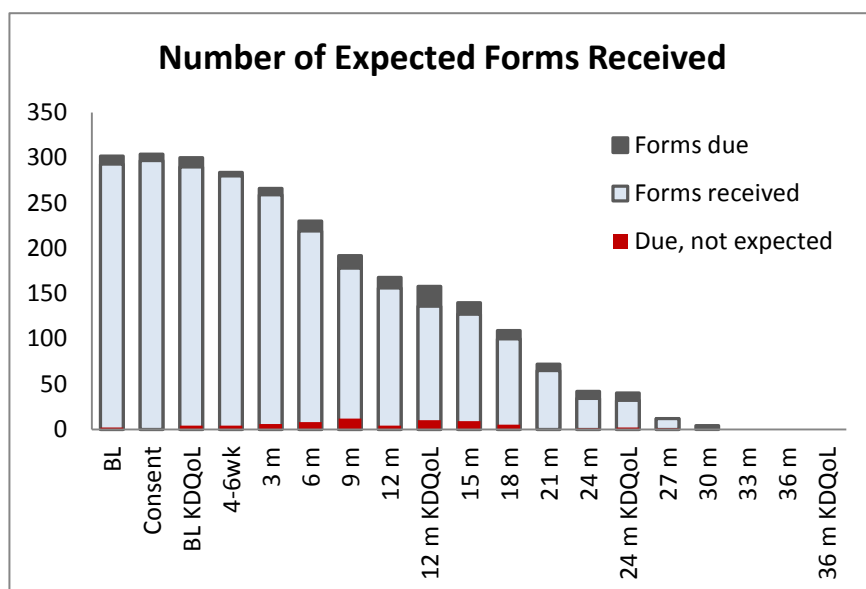
In the meantime, I wish you all the very best for a happy and relaxing Easter break

Best wishes,

Prof Sunil Bhandari



Form return rates



We have now received nearly 2,500 forms for STOP-ACEi.

This goes to show the huge effort put into the trial follow-up from all the site teams and patients.

Over 90% of the expected forms have been returned, which is great.

Please keep up the good work.



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.

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:

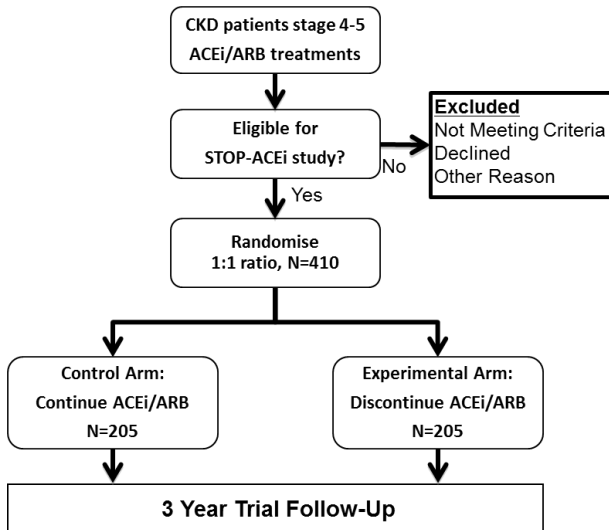
Friday 12 May 2017, 3pm

Monday 05 June 2017, 3pm

Wednesday 05 July 2017, 2pm



Study schema



Main Inclusion Criteria

- 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 within previous 24 months, calculated using trial-specific tool);
 - Treatment with either an ACEi or ARB or a combination of both for >6 months with at least 25% of the maximum recommended daily dose on the day of consent;
 - Resting blood pressure ≤160/90 mmHg;
 - 3 months of specialist renal follow-up at the time of entry into the trial;
 - Written, signed informed consent to the trial.
- Please see the study protocol for details.

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 Easter Closure

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

17:00, Thursday 13th April 2017 until

09:00, Thursday 20th April 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



NHS
National Institute for
Health Research

UNIVERSITY OF
BIRMINGHAM

