

STOP-ACEi Newsletter



Issue 3

July 2014

Full Title: Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease

Short Title: STOP-ACEi

Welcome to the third issue of the STOP-ACEi Newsletter!

Hull and East Yorkshire were the first STOP-ACEi site opened to recruitment on 2nd July 2014 and randomised their first STOP-ACEi patient on 11th July 2014.

Trial Design:

An investigator-led, multi-centre, open-label, randomised controlled clinical trial.

Trial Aim:

To test the hypothesis that stopping ACEi/ARB treatment, compared with continuing on these treatments, improves or stabilises renal function in patients with progressive stage 4 or 5 chronic kidney disease (CKD).

Population: 410 patients with stage 4 or 5 CKD that have progressive deterioration in renal function (fall in eGFR of >2 mL/min per year over last 24 months) and are currently receiving ACEi/ARB therapy.



The first STOP-ACEi patient has been recruited at Hull and East Yorkshire Hospitals NHS Trust

Hull and East Yorkshire Hospitals 
NHS Trust




National Institute for
Health Research

UNIVERSITY OF
BIRMINGHAM



Message from the Chief Investigator

Marie, The STOP-ACEi Trial Coordinator, who is central to our progress, has suggested I say a few words. I realise the summer weather may be a distraction but hope you are all energised to get involved with this important study.

First of all many thanks to everyone who has helped successfully launch the STOP-ACEi Trial. The trial is now underway and we are off the baseline in recruitment. I am grateful for the all centres, which total nearly 20 so far, who are committed to taking part and progressing to become active and allow us to head towards what I hope is a realistic target of 410 patients over the next 2 years. A good start is essential to keep us ahead of the curve.

It is clear from speaking with several nephrologists worldwide that this represents an important question and there is great equipoise in this area so I would encourage you to enrol patients.

Marie, I am sure will offer any guidance if required and I am more than happy to try and visit units when possible.

Best wishes,
Prof Sunil Bhandari

First patient enters STOP-ACEi trial

A huge thank you to the Renal Research team at Hull Royal Infirmary for recruiting the first STOP-ACEi patient just 9 days after the site opened to recruitment.

This is a major milestone for the trial. Thank you to all the investigators and research teams at all participating sites for your hard work in setting up STOP-ACEi at your centres and identifying prospective patients.

Your hard work is critical to the trial's success. Thank you.



Update on the MRC START project



Chief Investigator, Prof Sunil Bhandari, explains the aims of the STOP-ACEi trial in his video clip for the START website.

We will be embedding some methodological research into STOP-ACEi as part of the MRC's Systematic Techniques for Assisting Recruitment to Trials (START) project.

This will involve randomising some patients to receive the standard Patient Information Sheet and some to receive a PIS with a link to a website that contains video clips about the trial and video testimonies from patients that have experience of being involved in research. We are investigating whether access to this website will improve patient recruitment.

At the beginning of July 2014, we filmed the video clips for the website, featuring members of the renal research team at Hull Royal Infirmary. We're looking forward to see how the completed website looks!

For more information about START, please visit their website:

<http://www.population-health.manchester.ac.uk/mrcstart/>

BCTU are on the move!

The Birmingham Clinical Trials Unit moved offices within the University of Birmingham earlier in July 2014. The move went smoothly and we're settling well into our new offices in the Public Health building, part of the School of Health and Population Sciences.

Please note that our postal address and Marie Valente's phone number have changed, but all other contact details for the trial (e-mail, fax, websites etc.) remain the same.

The full contact details can be found at the end of this newsletter.



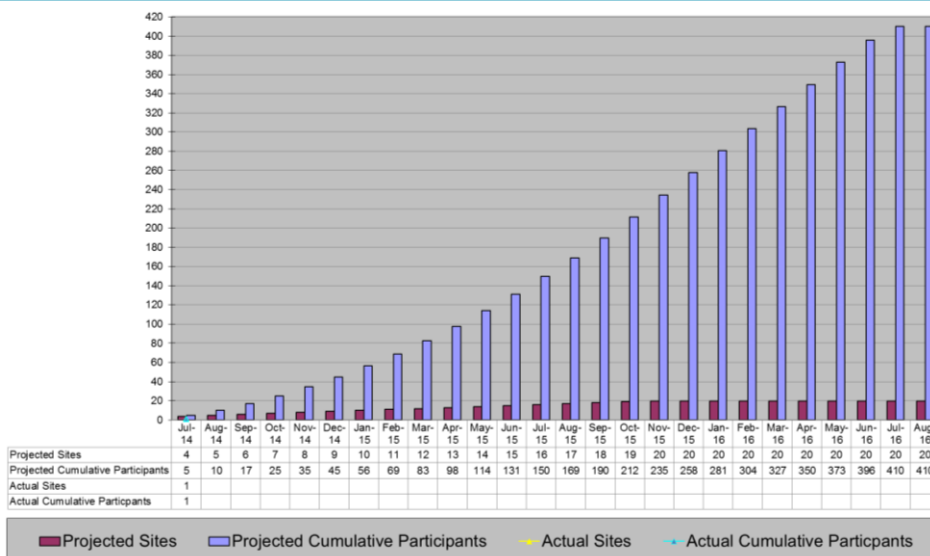
Setting up STOP-ACEi at your hospital

If you are interested in taking part in the STOP-ACEi trial, the following documents will be required as part of the set-up process:

- **Practical Arrangements Form:** This form contains some basic feasibility questions. If you would like BCTU to complete the SSI form on your behalf, please fully complete the form. If you will be completing your own SSI form, you need only complete page 3 of the Practical Arrangements Form.
- **Localised study documents:** Please send a copy of the letterhead you want to be put at the head of study documents (e.g. the PIS and consent form) to BCTU and we will adapt these for you.
- **CVs and GCP certificates:** We need CVs (signed and dated within the last 12 months) and up-to-date GCP certificates for all staff that will be working on STOP-ACEi at your site (i.e. all staff named on the delegation log or SSI form).
- **Honorary staff:** For any staff that do not have a substantive contract of employment with the hospital (e.g. honorary staff), we will also need a Letter of Access or a copy of the honorary contract.
- **SSI form:** This can be completed by yourselves or by BCTU. Please let me know if I can help with completion of the SSI form. Please send a PDF copy of the SSI form to BCTU when it has been fully signed/authorised.
- **Contract:** All sites need to have a fully signed contract in place before they can open to recruitment for STOP-ACEi. BCTU will provide a template contract which will need to be populated with site-specific information.
- **NHS permission:** Please let us know if we can do anything to help with obtaining local NHS approval. Please send a copy of your R&D approvals letter to BCTU when you have it.

Please contact Marie Valente, STOP-ACEi Trial Coordinator at BCTU, if you need any of the above forms or documents, or if you have any questions about trial set-up. We will do everything we can to help.

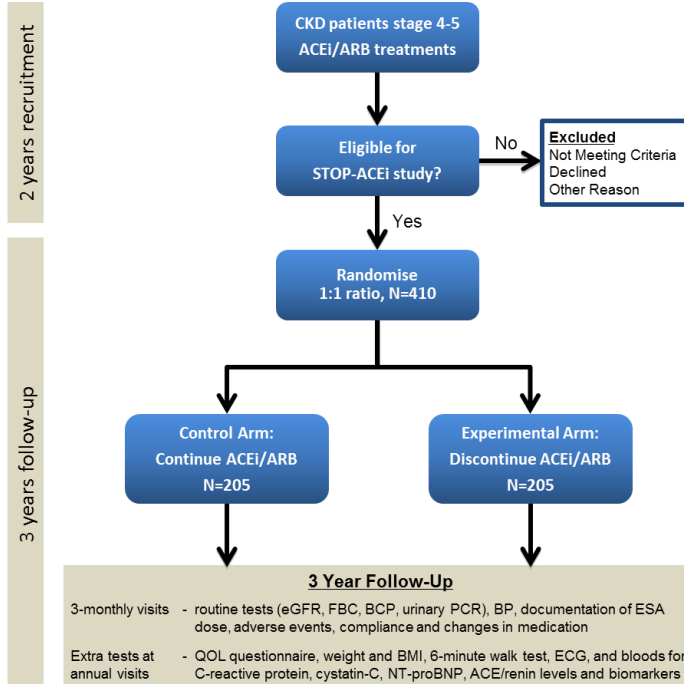
Recruitment update – 1 down, 409 to go!



STOP-ACEi will recruit 410 patients over its 2 year recruitment period. There will be approximately 20 recruitment centres across the UK.

Assuming that 1 new site is opened each month, every site will need to recruit at a rate of 1.15 participants per month for us to reach the recruitment target in time.

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 over previous 24 months, a tool to calculate this will be provided);
- 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.

STOP-ACEi study details:

Sponsor: Hull and East Yorkshire NHS Foundation 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

The STOP-ACEi study team are always here to help For further information about the STOP-ACEi study, please contact us:

STOP-ACEi Chief Investigator:

Prof Sunil Bhandari, Hull and East Yorkshire Hospitals NHS Trust, sunil.bhandari@hey.nhs.uk

STOP-ACEi Trials Coordinator:

Marie Valente, STOP-ACEi Study Office, Birmingham Clinical Trials Unit, m.valente@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
(Website is currently in development)

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

Please make a note of the new contact details for BCTU

