

# STOP-ACEi Newsletter



Issue 8

December 2015

**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

## Christmas closure



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

**13:00, Tuesday 22nd December 2015 until**



**09:00, Monday 4th January 2016**

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

## Message from the Chief Investigator

Dear all,

The “festive period” is upon us. It has been a tough year for all in many ways but I hope you can all give the STOP ACE study a final push for 2015 to push us towards the half way mark of recruitment. One patient from each centre would be fantastic. Like many studies we are approximately 4 months behind in recruitment but I am sure we can recover some lost ground.

The study has featured in the literature with the publication of the methods paper in NDT, presentation at the BRS and most recently the twitter feed. Indeed the question continues to be discussed by many.

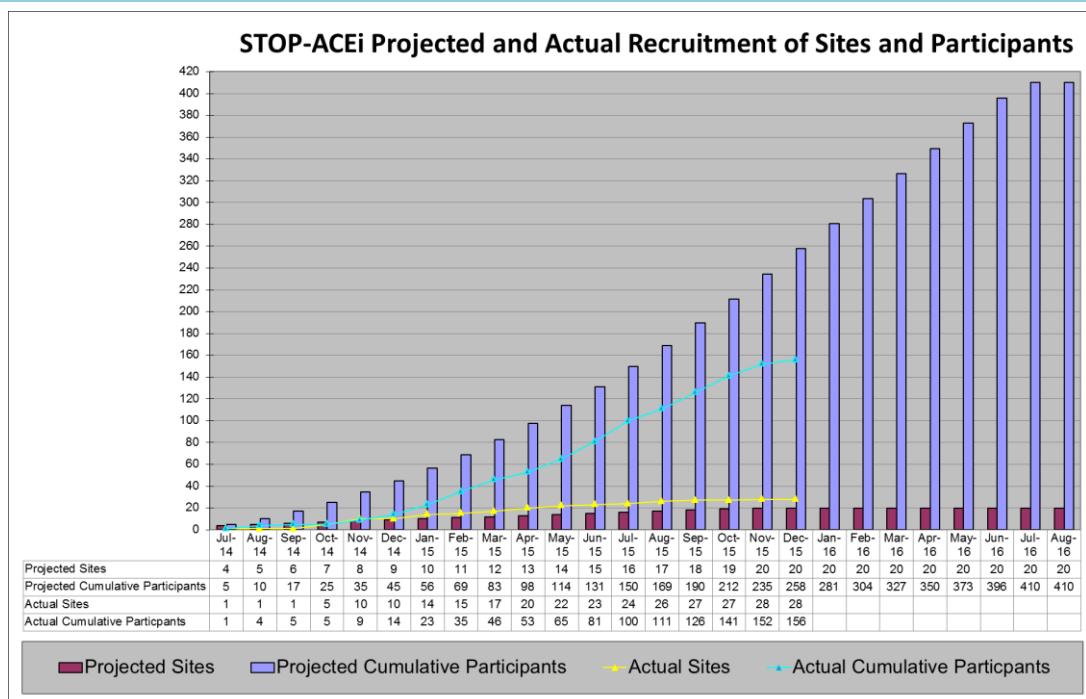
In the new year there will be another investigator meeting to review progress and discuss future trends in delaying renal progression. I would like to present some of the demographics to highlight the impressive stratification of the study.

I wish you all a restful Christmas break, well at least those not doing their 24/7 working, and a great new year.

Best wishes,  
Prof Sunil Bhandari



## Recruitment update – Over 150 patients recruited!



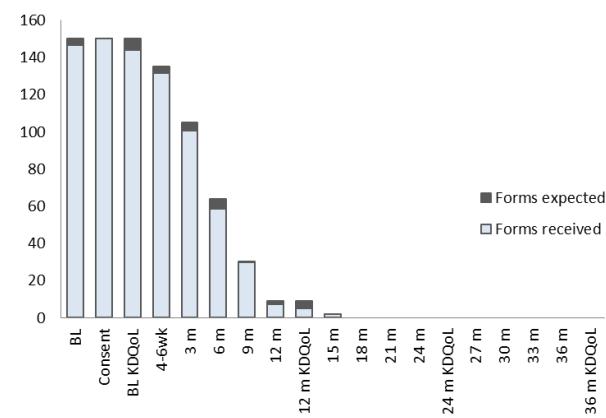
Thanks to your dedication and hard work with patient recruitment, there are now 156 patients taking part in STOP-ACEi. This is a fantastic achievement and we appreciate all the effort you put into identifying new patients. We are now around 4 months behind our projected target so your continued efforts remain essential for the success of this important trial.



### CRF return rates

We would like to take this opportunity to thank you for the excellent form return rates for STOP-ACEi. We have received around 95% of expected forms across all time points – thank you.

#### Number of Expected Forms Received



### 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:

Wednesday 20<sup>th</sup> January, 3pm



### STOP-ACEi Protocol published in NDT

A paper describing the rationale and design for STOP-ACEi was published online with Nephrology Dialysis Transplantation on 30 Sep 2015. Access the full article on the STOP-ACEi website:

[www.birmingham.ac.uk/stopacei/publications](http://www.birmingham.ac.uk/stopacei/publications)

### STOP-ACEi on Twitter

Follow us @STOPACEI\_trial for updates on trial progress.

## STOP-ACEi now open in 28 centres

28 renal centres across England and Wales are now recruiting into STOP-ACEi. We would like to extend a warm welcome to the team at **Southend University Hospital** who opened in November. Thank you for your hard work with trial set-up. We still welcome any new recruitment sites so please spread the word with your colleagues!

## Poster at ICTMC 2015

The trial statisticians for STOP-ACEi presented a poster on the analysis plans for the STOP-ACEi primary outcome data at the International Clinical Trials Methodology Conference 2015 in Glasgow in November.

## MHRA inspection at BCTU

The MHRA will be performing an inspection at BCTU on 14-17 Dec 2015. The inspection will not focus on STOP-ACEi, but the inspectors can review anything while they are here. The inspection is based at BCTU so we are not expecting inspectors to be visiting sites, but follow-up inspections including those at sites may follow.

## The STOP-ACEi team are always here to help

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

<b>STOP-ACEi Chief Investigator:</b> Prof Sunil Bhandari, Hull and East Yorkshire Hospitals NHS Trust, <a href="mailto:sunil.bhandari@hey.nhs.uk">sunil.bhandari@hey.nhs.uk</a>	<b>STOP-ACEi Trial Staff at BCTU:</b> Marie Valente, Trial Coordinator, <a href="mailto:m.valente@bham.ac.uk">m.valente@bham.ac.uk</a> Jamie Godsall, Data Manager, <a href="mailto:j.godsall@bham.ac.uk">j.godsall@bham.ac.uk</a>
<b>STOP-ACEi Trials Office:</b> <b>Website:</b> <a href="http://www.birmingham.ac.uk/stopacei">www.birmingham.ac.uk/stopacei</a> <b>E-mail:</b> <a href="mailto:STOPACEi@trials.bham.ac.uk">STOPACEi@trials.bham.ac.uk</a> <b>Telephone:</b> (0121) 415 9133 <b>Fax:</b> (0121) 415 9135	<b>Randomisation:</b> <b>Website:</b> <a href="http://www.trials.bham.ac.uk/stopacei">www.trials.bham.ac.uk/stopacei</a> (online randomisation open 24/7) <b>Telephone:</b> 0800 953 0274 (Available 9am-5pm, Monday – Friday)
<b>Postal address:</b> STOP-ACEi Trial Office Birmingham Clinical Trials Unit (BCTU) School of Health & Population Sciences Public Health Building University of Birmingham Edgbaston Birmingham B15 2TT	<b>BCTU Christmas Closure</b> Birmingham Clinical Trials Unit, including the telephone randomisation service will be closed from: <b>13:00, Tuesday 22<sup>nd</sup> December 2015 until 09:00, Monday 4<sup>th</sup> January 2016</b> The online randomisation and data entry service will still be available over the Christmas period.

## STOP-ACEi trial details:

<b>Sponsor:</b> Hull and East Yorkshire Hospitals NHS Trust Ref: R1578	<b>Funding:</b> The NIHR/MRC Efficacy and Mechanism Evaluation (EME) Programme. Ref: 11/30/07
<b>EudraCT no:</b> 2013-003798-82 <b>ISRCTN no:</b> ISRCTN62869767 <b>REC ref no:</b> 13/YH/0394 <b>IRAS/CSP ref no:</b> 138827	<b>Portfolio adoption:</b> As an NIHR funded study, STOP-ACEi has been adopted onto the NIHR CRN Portfolio. <b>UK CRN ref no:</b> 15908

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