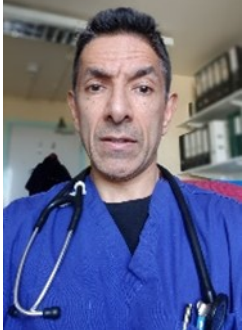


STOP-ACEi Newsletter

Issue 24, Dec 2021



Message from the Chief Investigator



It's been a long two years with huge challenges ahead. I hope you are all keeping as Omicron starts to take hold. However, a huge debt of thanks to you all and all of the patients who have been involved in the STOP-ACEi trial over the last 7 years. The TMG have been working hard to finalise the study and I am pleased to say that the database will be locked as early as the first week of January 2022. This will mark the start of the analysis of this important study which I am confident will impact on clinical practice.

Once the data is available we will share this with investigators at a confidential meeting prior to presenting. I would urge you all to consider other questions you might want to ask from the study for secondary papers and would be delighted for you all to get involved.

I am sure you are all more than ready, if not desperate, for some rest, joy and getting together (restrictions permitted) that Christmas will bring. It has been a busy year for everyone.

Finally, I would like to give particular thanks to Alastair Maund, our Trial Manager at BCTU over the most challenging last 2 years. Despite this he has, with the rest of the STOP-ACEi staff at BCTU, helped to steer the trial to the finish line. Alastair will be leaving the trial at the end of the year and I, and the TMG, wish him well in other pursuits.

Wishing you all a great festive "break" and an optimistic New Year.

Best Wishes,

Prof Sunil Bhandari

BCTU Christmas closure and SAE reporting Database Lock

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

17:00, Monday 20th December 2021 until

09:00, Monday 3rd January 2021

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

SAE reporting continues over Christmas

While there should obviously be no previously unreported SAEs at this point of the study, we understand that some PIs may wish to report some adverse events outside of the follow-up period.

Please e-mail any new SAE reports directly to the Chief Investigator and CC in the trial mailbox:

Sunil.Bhandari@nhs.net

stopacei@trials.bham.ac.uk

In order for the database to be locked, all sites will be sent a summary of all patient data which will require review and sign off by the Principal Investigator to confirm that all data is accurate.

These will likely be sent out in the first week of the New Year and, in order to ensure prompt locking of the database, we will be requesting that these PI sign offs are completed within 2 weeks of receipt.

Once these are sent out, any queries should be sent to the trial mailbox where they will be picked up and addressed as soon as possible.



The visit window is now ± 6 weeks to help with pragmatic follow-up.

Nearly 7000 forms have now been received for STOP-ACEi

Remember the extra research assessments at the annual visits:

- KDQoLSF™
- 6-minute walk test
- ECG
- Trial samples
- Weight

Remember to click 'Save' and then 'Submit' after you finish entering data into an eCRF

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STOP-ACEi is sponsored by Hull University Teaching Hospitals NHS Trust.

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Some Numbers...

While it's obviously impossible to put into words exactly how much effort has been put into this study by all of the staff across the dozens of recruiting sites, some incredibly impressive numbers help put some perspective on the study and just how much work has been put into it:

- Nearly **17000** eCRF parts have been submitted, corresponding to over **6500** forms completed
- Over **500** SAEs were collected and documented over the course of the trial, stringently checked and reported to relevant committees and authorities to ensure the safety of patients in the study
- Just under **4500** Creatinine values have been obtained, ensuring that the primary outcome will be successfully analysed and help inform clinical practice
- Over **400** staff across **39** sites have been involved with the study over **7** years, ranging from consultant nephrologists and cardiologists to research nurses to data managers and research governance staff.
- Nearly **10000** antihypertensive medications have been documented along over all of the patient follow-up, as ensuring adequate BP control has been paramount during this study.
- In total, over **600000** data items have been entered by site staff to produce the dataset for analysis



BCTU Staff update

Alastair Maund will be leaving the STOP-ACEi team and BCTU at the end of the year, following 2 years as Trial Manager. He will be moving to another clinical trials unit in the public sector and he's incredibly thankful for all the individuals he's been able to work with; those at BCTU, those in the Trial Management Group and oversight committees and those at sites.

In light of this, please ensure any queries regarding STOP-ACEi are directed to the trial mailbox and not the personal mailboxes of BCTU staff, to ensure they can be picked up in a timely manner.

Trial Closedown

In the New Year, close down of the study can also begin. This will involve a checklist being sent out of all items that should be contained within the Investigator Site File at each participating site. This will require checking, and any missing documents will require requesting from BCTU.

Unfortunately this does not mean that the trial can be archived, as this must wait until the publication of the final report to NIHR, which will likely occur in summer 2022.



Study Contact details

Chief Investigator

Prof Sunil Bhandari
Hull University Teaching
Hospitals NHS Trust
sunil.bhandari@nhs.net

STOP-ACEi Trial Staff at BCTU

Hugh Jarrett
(Team Leader)
Alastair Maund
(Trial Manager)
Aisha Khan
(Data Manager)
Charmaine Hunt
(Data Manager)

Website

www.birmingham.ac.uk/stopacei

Email

STOPACEi@trials.bham.ac.uk

Twitter

@STOPACEi_trial

POSTAL ADDRESS

STOP-ACEi Trial Office,
Birmingham Clinical Trials
Unit (BCTU)
Public Health Building
University of Birmingham
Birmingham
B15 2TT

