

STOP-ACEi Newsletter

Issue 18, April 2019



Message from the Chief Investigator

Thank you for your continued efforts in helping see this important study get closer to the finish line. Hopefully for many of you the workload is starting to reduce as patients reach their 3 year completion landmark. However it is imperative that we maintain retention of those patients yet to finish, as well as focusing on missing data for each site.

Hopefully if all sites can send as much data as possible we can ensure that when we get past the finish post, I hope in 2021, we will be in a great position to analyse and report the data as quickly as possible. I am hoping we will be in a position to report on the baseline data for the study in the near future.

We have just submitted a contact variation to extend the study due to the longer time to recruit and I am hopeful the NIHR will be receptive. We have recruited to completion and already over 40% of the patients have completed follow-up.

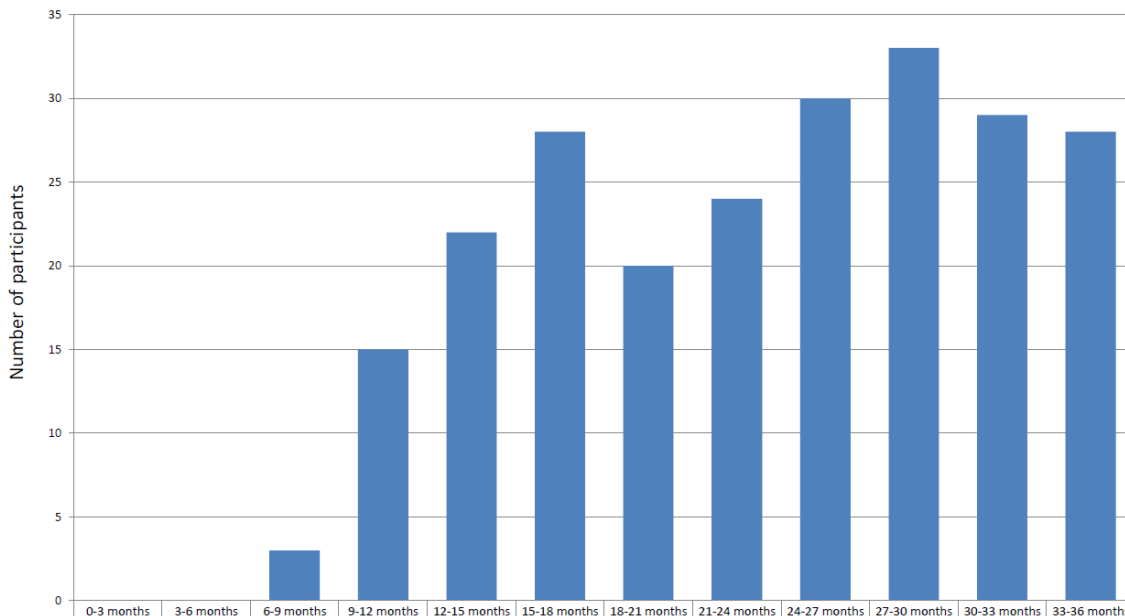
Wishing you all a great break as Easter fast approaches.

Prof Sunil Bhandari

Current Progress

Around 180 patients have already completed STOP-ACEi follow-up. Follow-up is continuing well for over 200 patients that are still on trial. The below graph shows which time point the remaining participants have reached. Please keep up your good work with completing the follow-up visits. The more data we get for the trial, the more powerful the study results will be.

Follow-up time point of participants in STOP-ACEi



BCTU Easter Closure & SAE Reporting



Birmingham Clinical Trials Unit will be closed from Thursday 18th April and will re-open on Thursday 25th April. **SAE reporting continues as normal over this period.**

Over 5,000 follow-up forms have been received

Don't forget about the quality of life questionnaires (KDQOL-SF™) at the annual visits

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

STOP-ACEi is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership

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

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Research Nurse Teleconferences

Thank you to those who attended the last teleconference in March. We are continuing to see good attendance at these teleconferences so we will continue holding them through the follow-up period.

The next Research Nurse teleconferences are scheduled for:

- Wednesday 12th June 2019, 3pm
- Thursday 12th September 2019, 2pm
- Tuesday 3rd December 2019, 3pm

Data Returns

The overall data return rate for the trial continues to hover around an encouraging 95%. The tables below show our top sites for data returns. The majority of sites have a data return rate of over 90%. Thank you for all your hard work.

Larger Sites (≥10 STOP-ACEi patients)	Data Return Rate
King's College Hospital London	99.3%
Queen Elizabeth Hospital Birmingham	98.7%
Royal Preston Hospital	98.6%
Royal Liverpool University Hospital	97.9%
Birmingham Heartlands Hospital	97.6%

Smaller sites (<10 STOP-ACEi patients)	Data Return Rate
Royal Sussex County Hospital	100.0%
Huddersfield Royal Infirmary	99.5%
York Hospital	99.5%
Royal Free Hospital London	98.6%
University Hospitals Coventry & Warwickshire	98.5%

In Other News

- The MHRA has recalled several batches of Irbesartan and now Losartan due to concerns about contamination. Further details can be found in the MHRA's [latest press release](#). Patients have been advised to continue taking their medications and the recall will mostly affect pharmacies. There is no specific action needed for STOP-ACEi.
- Our Sponsor has changed its name to Hull University Teaching Hospitals NHS Trust.
- Happy Easter from the STOP-ACEi team—we hope you can enjoy a well earned break.



GDPR Amendment Reminder

Following on from the email sent to participating sites in December 2018. Please remember that any STOP-ACEi participants currently in follow-up should be given the GDPR addendum. This should be documented in the patient's medical notes.

Once all of your patients have been given the addendum please let the team at BCTU know. We will soon be asking for an update from sites who have yet to confirm all patients have been given the additional information.



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Next Newsletter due
Summer 2019