

STOP-ACEi Newsletter

Issue 19, August 2019



STOP-ACEi extension approved!

We are delighted to confirm that the EME funding committee have agreed to support an extension to the STOP-ACEi trial. Patient recruitment completed in June 2018, which was 23 months later than anticipated, so this extension will allow the planned 3 years of follow-up to be completed for all the participants. This is really fantastic news as it will ensure as complete a dataset as possible for analysis of the primary outcome, which is measured at the 3 year time point.



Message from the Chief Investigator

I hope you all have a chance to get some down time with the family away from the pressures of the NHS and Brexit. With the relentless clinical pressures, I am deeply grateful for your ongoing commitment to the study. Over 50% of the patients have now reached the 3 year endpoint.

I am also encouraged by the continued interest in the STOP-ACEi trial and the number of observational studies published on the topic. The observational study published in this month's JASN, examining a huge patient cohort over 15 years, continues to emphasise the lack of ACEi/ARBs use in over 50% of patients. Clinicians remain uncertain about what to do in advanced CKD with ACEi/ARB use. Hopefully we can provide an answer.

The NIHR have fully supported our extension to ensure we get a result, but most importantly it allows us to feedback the final results to all the patients who have so generously taken part in the study.

We continue to clean the data and I would be grateful if you can answer any queries sent so we can rapidly analyse the data once the study completes. Currently we hope to get the baseline data complete and share these with all in a future Investigator Meeting.

Looking forward to seeing you all in the near future but please do not hesitate to get in touch at any time.

Prof Sunil Bhandari



Substantial Amendment 12

Documents relating to a trial Protocol amendment were sent out to all the STOP-ACEi collaborators and R&D departments on 22-Jul-2019. To address a couple of common questions:

- We do not yet have the outcome of the REC review and HRA approval. These will be circulated as soon as we have them.
- Will this change how we follow-up patients? You should read the full details in the amendment documents, but the practical changes are quite minor and will hopefully make things easier for research staff and participants. The main practical differences are: the acceptable visit window will be more lenient, patient diaries are no longer needed, you have more time to report unrelated SAEs, and a patient thank you letter has been added.

Thanks to your efforts, STOP-ACEi has accumulated over 1000 patient years of follow-up

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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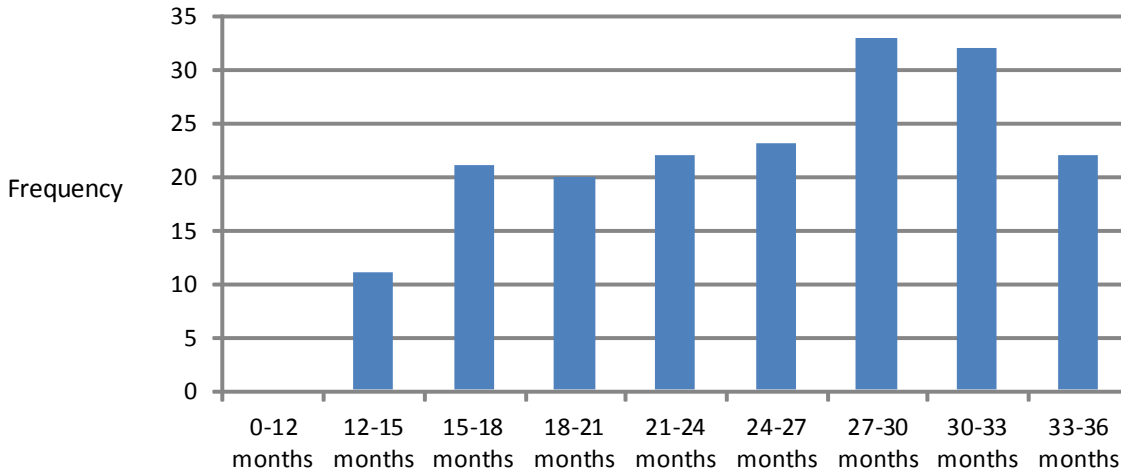
Current Progress



Over half of the participants recruited into STOP-ACEi have now completed their trial follow-up, while around 185 participants are continuing with their follow-up. The below graph shows which time point the remaining participants have reached, and all of them are into at least their second year of follow-up now. Please keep up your good work with the follow-up visits.



Follow-up time point for STOP-ACEi participants



Data Manager Update

After 4 years working on the trial, Jamie Godsall has now left STOP-ACEi to work on another project within BCTU. Aisha Khan is now the Data Manager for STOP-ACEi and is quickly settling into the role. Make sure you send any e-mails to the STOP-ACEi mailbox so these can be picked up promptly.

Research Nurse

Teleconferences

The next Research Nurse teleconferences are scheduled for:

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



GDPR information

The GDPR documents for STOP-ACEi were sent out in December 2018. If you haven't already done so, please ensure all participants receive this information, and confirm with the trial office when this is done.

Data Returns

Data returns are very good for the trial at around 94% overall. Of the 39 STOP-ACEi sites, 30 have a return rate of over 90%. This is a real testament to the hard work you put in with patient follow-up, and the dedication of all the participants to continue attending follow-up visits. Thank you.

Top 10 centres for data returns:

Royal Liverpool	100%
Ysbyty Glan Clwyd	100%
Daisy Hill, Newry	100%
Royal Shrewsbury	99.7%
University Hospital Coventry	99.6%
Calderdale & Huddersfield	99.6%
Queen Elizabeth, Birmingham	99.1%
Leicester General	98.9%
Charing Cross, Imperial	98.7%
Royal Sussex	98.5%

Baseline data

We are looking to publish some of the baseline data for the STOP-ACEi trial patient cohort, so please respond as soon as you can if we send any queries for the baseline data.

Study Contact details

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Next Newsletter due
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