

# STOP-ACEi Newsletter

Issue 20, December 2019



## Message from the Chief Investigator

I want to thank you all for another year of hard work towards this study. We had the great news earlier this year that NIHR had approved the trial extension. Follow-up is continuing well with good data returns. We've had the final visit data for around 180 participants now, which is great. There are of course still lots of visits left to do, so please try to keep up the momentum through 2020.

One thing I would ask all the investigators to consider is whether treatment compliance can be re-established for any patients where this has changed. Of course, only where this is clinically appropriate, and the investigator has discretion on this.

I wish you all a happy Christmas break and New Year, and I hope you all manage to get a little time to rest and enjoy time with family and friends.

Best wishes,

Prof Sunil Bhandari



## BCTU Christmas closure and SAE reporting

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

13:00, Friday 20th December 2019 until

09:00, Thursday 2nd January 2020

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

### SAE reporting continues over Christmas.

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

[Sunil.Bhandari@hey.nhs.uk](mailto:Sunil.Bhandari@hey.nhs.uk)

[stopacei@trials.bham.ac.uk](mailto:stopacei@trials.bham.ac.uk)

These will be monitored over the Christmas break.



## Thank you

Many of you helped prepare the trial data for an analysis presented in the latest meeting of the trial's Data Monitoring and Ethics Committee earlier in December.

This committee reviews the trial data and helps ensure the trial is run safely and effectively, so it's really important they can review the most complete and clean data possible.

Thank you to everyone for your prompt responses to queries over the last couple of months.

The visit window is now  $\pm 6$  weeks to help with pragmatic follow-up.

Nearly 6000 forms have 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

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.

ISRCTN62869767



## Trial treatment compliance



In STOP-ACEi, participants are randomised to either continue using ACEi/ARBs or to discontinue these treatments. To ensure that the trial is as good a test as possible of the two treatment interventions, compliance with the allocated treatment needs to be as close as possible, if this is clinically appropriate.

We understand that, sometimes, it might be necessary to deviate from a patient's randomised treatment allocation. Sometimes this will be long-term and other times only a temporary change is needed, such as a 'drug holiday'.

We'd like to encourage all PIs to review the participants under their care for STOP-ACEi and consider whether it is possible for trial treatment compliance to be safely re-established for any participants that are not currently on their randomised treatment allocation.

## Data returns & patient follow-up

Data completeness and quality is a top priority through the follow-up phase of the trial. Data returns remain very good for STOP-ACEi. 22 of the STOP-ACEi sites have a form return rate of over 95%, which is excellent.

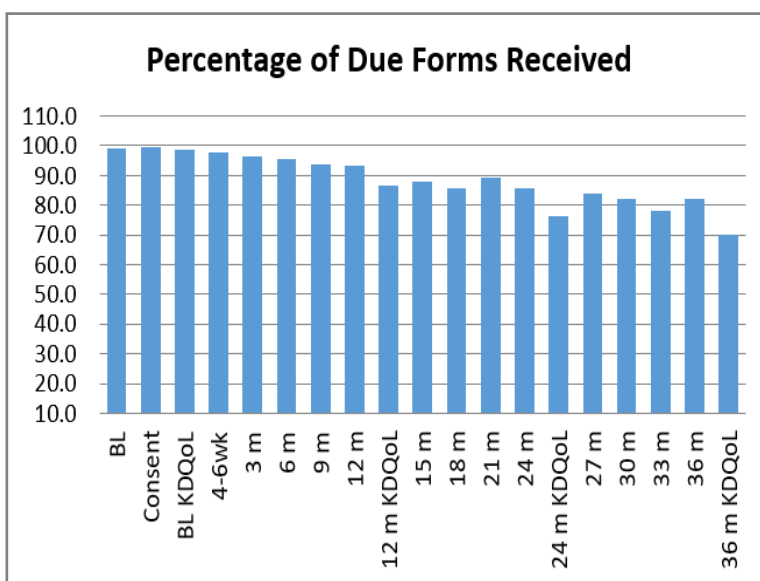
Thank you for your huge efforts with the patient assessments and returning the data promptly.

However, the form returns do get lower for the later time-points. Please remember to complete the data and submit your forms as the patient progresses through the trial. Please let us know about any missed visits or quality of life forms.

## Research Nurse Teleconferences 2020

Please add the dates for next year's Research Nurse teleconferences to your calendar:

- Wednesday 22 January 2020, 2 pm
- Thursday 02 April 2020, 10 am
- Tuesday 23 June 2020, 2 pm
- Monday 14 September 2020, 10 am
- Wednesday 09 December 2020, 2 pm



## Requested updates

Please ensure you have sent all the confirmations previously requested.

- Confirmation of providing GDPR information to participants—originally requested 06-Dec-2018
- Confirmation of updating ISF following Sponsor name change—originally requested 08-Apr-2019
- PI Protocol signature page and R&D confirmation (where applicable) for Substantial Amendment 12—originally requested 30-Sep-2019

Please contact the trials office for any queries on this.



### Study Contact details

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