

STOP-ACEi Newsletter

Issue 23, April 2021



Message from the Chief Investigator

As we hear the news of 30 million people receiving their first COVID-19 vaccine dose, we hopefully find ourselves able to look forward to the coming months and yet more good news as the country and the world slowly begin to recover. This last year has seen a tremendous effort from the hundreds of thousands of healthcare professionals in the country in order to provide care and treatment for the nation, and we should all be proud.

The STOP-ACEi study has been fortunate to avoid as many disruptions or suspensions as many other clinical studies, and your efforts have been outstanding to ensure the study has continued as smoothly as possible. Less than 3 months remain until the final patient is expected to complete follow-up, the end of the study is very much in sight and we trust that you all will continue with the outstanding work that you have all provided to the study.

With the number of observational studies published regarding RAS Inhibitors and advanced CKD, including the JASN publication earlier this year involving over 10,000 patients (which can be found here: <https://jasn.asnjournals.org/content/32/2/424>), it's clear that many eagerly await the results of the STOP-ACEi study. This year, we expect to be able to finally provide these results and ensure the highest standard of care for our patients.

Happy Easter to you all, and I hope you are all able to safely spend some quality time with friends and family over this Easter period.

Best Wishes,

Prof Sunil Bhandari

BCTU Easter closure and SAE reporting

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

17:00, Thursday 2nd April 2021 until

09:00, Thursday 7th April 2021

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

SAE reporting continues over Easter.

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

KDQoL Questionnaires

During the COVID-19 pandemic, we have been incredibly thankful for all of the efforts of staff to ensure that as much data is collected as possible. The return rates of KDQoL questionnaires is understandably lower, especially owing to increased difficulties in administering the questionnaire. Many sites who have continued to complete these have done so via telephone or through posting the questionnaires to patients.

In the event that the KDQoL questionnaire has not been completed by the patient (either through not returning the form or being unable to complete via telephone), please ensure that the corresponding question on the Follow-Up CRF is completed correctly (with a reason provided in the 'Notes' section), and the corresponding KDQoL Questionnaire eCRF is deleted.

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

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

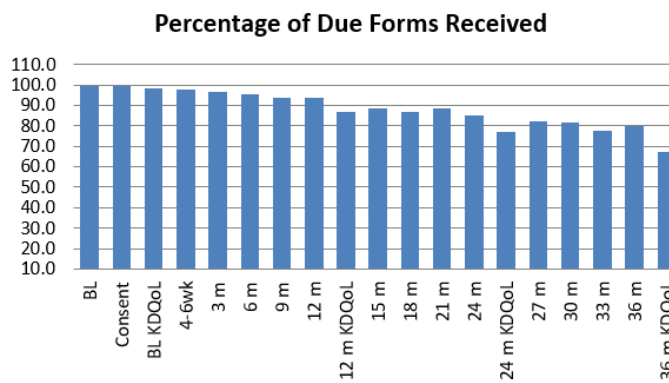
STOP-ACEi is sponsored by Hull University Teaching Hospitals NHS Trust.

ISRCTN62869767

Data Return and Follow-Up Completion during COVID-19

The outstanding performance with regards to data completion and data returns has continued this year, thanks to the effort of you all. The total return rate stands at 93.2%, with 12 sites boasting a return rate of over 99%, and 27 sites with a return rate of over 90%.

As we continue to work through the data that has been submitted and generate queries, we know that some sites may receive a large number of queries. We appreciate all efforts that are made to respond to these queries in a timely manner, and if any assistance is required, then please contact the STOP-ACEi mailbox and we will endeavour to help as best we can.



Top 10 Sites by CRF Return Rate

Royal Sussex County Hospital	100.00%
Leicester General Hospital	100.00%
The Royal Liverpool University Hospital	100.00%
York Hospital	99.52%
Nottingham University Hospitals NHS Trust -	99.49%
Queen Elizabeth Hospital Birmingham	99.41%
Royal Shrewsbury Hospital	99.37%
Huddersfield Royal Infirmary	99.36%
King's College Hospital (Denmark Hill)	99.33%
Royal Free Hospital	99.16%

BCTU Staff update

As of March 2021, Charmaine Hunt has joined the STOP-ACEi team as a Data Manager to assist with data cleaning for the last few months of the study. As always, ensure that all queries are sent to the STOP-ACEi trial mailbox so that these may be addressed promptly.

In addition, as of March 2021, Hugh Jarrett has taken over from Bill McKinnon as Team Leader for the STOP-ACEi study.

BCTU Trial Database downtime

On the 8th and 9th April 2021, there is scheduled downtime of some BCTU servers to allow for the migration of servers. As a result, the STOP-ACEi remote data capture database, as well as many other BCTU trial databases, will be unavailable across these dates, including online randomisation for a number of studies. Please plan any proposed data entry for STOP-ACEi around these dates.

Sample Shipments

As we approach the end of the study and a large number of sites do not have any patients left on follow up, many sites will want to begin arranging sample shipments to the central lab in Hull. In order to do this:

- Send through a copy of the completed freezer log, as well as preferred days of collection and the address of collection, to the STOP-ACEi mailbox.
- Address any queries that we may raise regarding the freezer logs promptly so that the shipment may be arranged.
- Once this has been raised with the courier, we will let you know the date of collection as soon as possible. Dry ice is provided by the courier.
- Once the samples have been collected by the courier, please let the STOP-ACEi team know via email

The current lead time from first quote from the courier to the date of collection is around 2 weeks.



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