STOP-ACEi Newsletter

Issue 17, December 2018



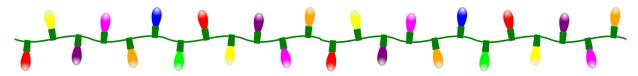
Message from the Chief Investigator

About a third of STOP-ACEi patients have now reached their final, month 36, visit. There are of course still a lot of visits left to do and a lot of data left to collect. My big request is to keep going, especially for annual visits, to maximise and maintain the quality of data collected. STOP-ACEi is on the world stage of "eagerly" anticipated trial results. PIVOTAL has led the way and I hope that STOP-ACEi can follow with similar success.

As Christmas fast approaches, I do hope you will all have time to enjoy the festive spirt and get a little time with family and friends or just a well-earned break. I am really indebted to all the PIs, Clinicians, Nurses and research staff who have contributed so much already to this, I hope, future landmark UK study. It will change, or at least influence, clinical practice. I really appreciate your ongoing support.

Best Wishes for 2019.

Prof Sunil Bhandari



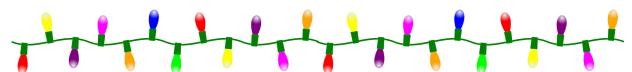
BCTU Christmas Closure & SAE reporting

Birmingham Clinical Trials Unit will be closed from Friday 21st December and re-open on Thursday 3rd January 2019. **SAE reporting continues over Christmas.**

Whilst BCTU is closed, please e-mail any new SAE reports directly to the Chief Investigator and CC in the trial's NHS.net account. These will be monitored.

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Data Queries and Data Clarification Forms

Thank you to all the Research Nurses and Data Managers who responded quickly to a recent rush of data queries. These were prompted by an interim analysis of the data by our Stats team here at BCTU. These queries will continue as we try and clean the data as much as possible.

As part of a general move towards Data Clarification Forms (DCFs) to raise and track queries, all data queries will now be sent on DCFs. For guidance on this please have a read of the <u>STOP-ACEi Guidelines</u> for Data Entry on the trial website.

Please can we remind everyone to use the 'Notes' field at the top of every eCRF to let us know of any missing data or to inform us of any discrepancies between trial visits. A lot of people are already doing this and it has dramatically reduced the number of queries raised.

Over 4,700 follow-up forms have been received

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

Please try and ensure as many patients as possible complete the quality of life questionnaires (KDQOL-SF™)

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

STOP-ACEi is sponsored by Hull & East Yorkshire Hospitals NHS Trust

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Research Nurse Teleconferences

The next research nurse teleconference is scheduled to take place on Wednesday 12th December 2018 at 2pm. An invite to this will be sent out shortly.

The next teleconferences are scheduled for:

- Wednesday 6th March 2019, 2pm
- Monday 10th June 2019, 3pm

STOP-ACEi website crashes internet*

*Not really

We recently found out that STOP-ACEi webpages were responsible for over 5% of all traffic to the BCTU website. The STOP-ACEi 3-monthly follow-up form was the most popular CRF in the whole unit and the protocol was the second most popular.

Surprisingly, the guidelines for doing the 6-minite walk test were viewed a massive 235 times in just the past month!



Study Contact details

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Next Newsletter due March 2019

Data Returns

The amount of data being received for the trial is growing all the time. The overall data return rate for the trial has been around 95% for some time now. This is excellent and we want to thank every site for taking the time to enter the data online and respond to email reminders. To encourage some friendly competition the below tables show our top sites for data returns. But we do want to emphasise that the vast majority of sites have a data return rate of over 90%.

Larger Sites (≥10 STOP-ACEi patients)	Data Return Rate
Royal Preston Hospital	100.0%
King's College Hospital	99.9%
The Royal Liverpool University Hospital	98.8%
Queen Elizabeth Hospital Birmingham	98.5%
Birmingham Heartlands Hospital	97.2%

Smaller sites (<10 STOP-ACEi patients)	Data Return Rate
Daisy Hill Hospital	100.0%
Glan Clwyd Hospital	100.0%
University Hospitals Coventry & Warwickshire	99.6%
Leicester General Hospital	99.2%
St Helier Hospital	98.9%

In Other News

- Birmingham Clinical Trials Unit recently celebrated it's 21st Anniversary. Since its inception in 1997, BCTU has supported a wide range of clinical studies across a wide spectrum of clinical conditions and in diverse populations.
- <u>@STOPACEi_trial</u> now has over 320 followers on Twitter. For news from across BCTU please also follow <u>@BhamCTU</u>
- The STOP-ACEi database will be unavailable before 8:30am on 10th, 17th & 20th December 2018.
- Merry Christmas and a happy New Year from Jamie, Marie and everyone here at BCTU.







