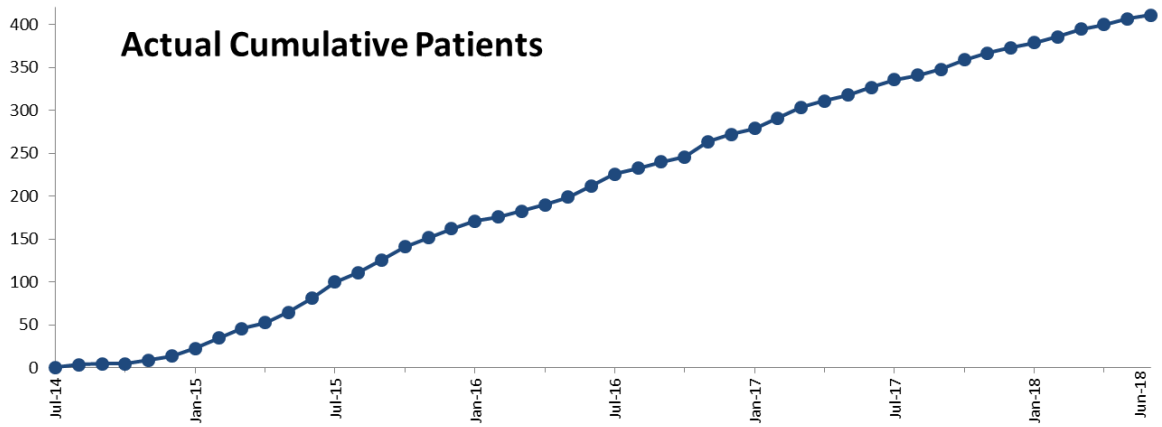
STOP-ACEi Newsletter

Issue 15, June 2018

www.birmingham.ac.uk/stopacei

STOP-ACEi Reaches Recruitment Target

After a lot of hard work the STOP-ACEi trial reached its recruitment target of 410 patients earlier in June and took us one step closer to answering an important clinical question—whether it is best to stop or continue use of ACEi and ARBs in advanced CKD. Finishing recruitment on any trial is always cause for celebration, so a big thank you to all our sites. The good news is that we'll stop bothering you about screening and recruitment now, the bad news is we're going to start talking more and more about follow-up and retention. For now enjoy the moment, but please don't forget to schedule in those follow-up visits!



Message from the Chief Investigator

I hope you are all enjoying the warm weather, football, cricket and rugby. England are doing well, at least in the football and cricket. STOP ACEi has achieved yet another landmark; we reached our required recruitment target of 410 patients on June 14th 2018 with Queen Elizabeth Hospital Birmingham recruiting the 410th patient. It all started back in July 2014 when the first patient was randomised in Hull. This has been a remarkable achievement from the 37 renal units in the UK who have recruited patients to a trial I hope will shape future practice and guidelines.

We are now in the key period of follow-up over the next 3 years to ensure we obtain as much data as possible to answer this important question. Our primary objective is to assess the impact of ACEi/ARB in patients with advanced CKD on the change in renal function over a three year follow-up period. I am sure the results, when the study is complete, will be of huge interest to healthcare professionals looking after patients with kidney disease all over the world. These patients have committed a huge amount of time to the study and we are therefore indebted to them. We are obliged and in a sense ethically committed to complete this study for their benefit, and provide them with the final results.

Finally, I am planning an investigator meeting for all the centres involved in the trial to update you with the baseline data and plans for the study during this follow-up period. I am keen we maintain the momentum. Please look out for more information about this in the near future.

Best wishes,
Prof Sunil Bhandari

Top Recruiting Sites by Number of Patients:
Hull Royal Infirmary
QE Hospital B'ham
Northern General
Imperial College London
King's College Hospital

Top Recruiting Sites by Recruitment Rate (pts per months open):
Epsom & St Helier
Hull Royal Infirmary
Northern General
Imperial College London
Nottingham

37 of 39 open STOP-ACEi sites recruited at least 1 patient

22 out of 39 sites recruited to or above their local target

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

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Data Follow-up and Out of Schedule Visits - FAQ

We're getting an increasing number of questions regarding trial follow-up and data collection. Below are a selection of questions and brief responses. Fuller responses to these questions can be found in the FAQ section of the website.

A STOP-ACEi patient doesn't want to carry on with trial follow-up. What should I do?

Taking part in research is completely voluntary. But wherever possible, we want to collect as much of the trial outcome data as we can.

There are different types of withdrawal for STOP-ACEi. So if a STOP-ACEi participant asks to withdraw from the trial, please clarify which aspects they want to withdraw from. Usually, patients that withdraw want to stop coming in for trial-specific visits or want to opt out of specific research assessments, but are happy to continue sharing their data. It is essential to make a clear record of this discussion with the patient.

Lots of the data we collect for STOP-ACEi is available from routine monitoring, so if the patient wants to withdraw from full trial follow-up, but is happy to let us continue receiving these data, please continue with the patient's data collection based on their medical records. At each follow-up time point, complete what you can of the CRF from the patient's case notes. To minimise queries, make it clear which data are missing in the notes section of the eCRF.

I couldn't see the patient for trial follow-up at their last clinic visit. Can I use their medical records and routine tests to complete the CRF?

Yes. Lots of the data we collect for STOP-ACEi are available from routine clinical monitoring. It is fine to use these to complete the CRF. It is better to report what you can, rather than miss a visit altogether. However, there are few things to be careful of:

- Make a record of the reason for any Protocol deviations. For example, if assessments have been missed, or any visit assessments are outside the permitted visit window.
- We recommend that you make a record to make it clear what is the source data for the trial visit, especially if this is pieced together from multiple sources.
- When you input the data on the eCRF please explain what data are missing and why in the 'notes' field.

One of our STOP-ACEi participants does not have a scheduled clinic visit in time for the next trial follow-up due date. What should I do?

The visit schedule forms part of the Protocol for the STOP-ACEi trial, so a record should be made if there is a deviation from the schedule. The visit schedule for STOP-ACEi was designed to fit in with the normal clinic follow-up frequency for patients with advanced kidney disease, but this might not always coincide, for example if the clinic follow-up schedule is altered following an admission, or the patient requires more/less frequent follow-up. You should always aim to see the patient within the permitted visit window, but if this is not possible or the patient declines to attend, it is better to obtain the trial data late than not at all.

If the participant is not seen within 6 weeks of a visit due date (i.e. a visit is nearer to the next trial due date), the time point has been missed. If this happens, please let us know, and make a record of the deviation and the reason.

In Other News

- We'll be taking a break from research nurse teleconferences over the summer. They'll be back in September with a new format focussed on follow-up and retention. Thank you to everyone who has called in over the years.
- @STOPACEi_trial now has close to 300 followers on Twitter.
- The CRF return rate for expected data is around 94%. Please keep completing those eCRFs.
- You may have noticed that the format of the newsletter has changed. Feedback on the new look and any suggestions regarding content is very welcome.

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Next Newsletter due September 2018