REVIVED-BCIS2 Newsletter Issue no.30 May 2016



Regional Meetings

The 4th May at Royal Bournemouth Hospital was a great success with representatives from 8 sites and engaging talks and many cases reviewed. Many thanks to Peter O'Kane and the Bournemouth team for hosting the meeting. A second investigator meeting will be held on the 12th May at Barts Heart Centre, London hosted by Roshan Weerackody and the team at Barts. If you would like to attend this meeting, please email revived@LSHTM.ac.uk.

Save the date! There is an additional regional meeting being planned for 6th June in Manchester. This will be an evening meeting coinciding with the end of the first day of the BSC annual conference. Planning for this meeting is still in the early stages but if you would like to attend, please keep this evening free in your diaries. More details will follow shortly.

Thoughts on the STICH Extension Study (STICHES) - Divaka Perera

STICHES, the long-term follow-up phase of the STICH trial, reported at ACC in Chicago last month (NEJM 3rd April). In STICH there was no survival benefit with CABG, compared to medical therapy alone, at 5 years; in fact, there were more deaths in the surgical group early on. STICHES shows that in patients who survive the initial excess of death related to CABG, a survival advantage does become apparent at around 10 years. The accompanying editorial concludes that "the results of this trial should change our clinical approach to patients with heart failure. Early identification of a possible ischemic cause for left ventricular systolic dysfunction should be pursued with the potential of improving long term survival". This corroborates the view that early angiography (and imaging such as MRI, in whichever sequence is preferred) is both justified and indicated in patients with LV dysfunction of unknown cause.

It is tempting to extrapolate these data to PCI, which may offer all the benefits of revascularisation shown in STICHES without the morbidity and mortally associated with CABG. However, as the NEJM editorial highlights, to date, "there is no evidence that percutaneous coronary intervention prolongs survival in (ischaemic cardiomyopathy)". REVIVED is designed to answer this question and we have a unique opportunity to deliver this trial in the UK.

The paper can be accessed here: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1602001

"One patient" campaign

We have now randomised 177 patients, passing the 25% landmark. While this is a great achievement and REVIVED is already the largest RCT to date of PCI for ischaemic cardiomyopathy, the recruitment rate needs to be lifted urgently.

Our aim is to get to 30%, or 210 patients, by the end of June - **One patient from each centre** (on average), **in the next 6 weeks**. The trial really needs each of you to dig deep and try to deliver this, to make sure we stay on track and keep our funding secure.

Payments to sites

This is a reminder about claiming your payments for recruitment. You should be receiving regular updates on what you can claim for. All invoices should be accompanied by a purchase order number.

Queries about invoices should be sent to Josenir Astarci (josenir.astarci@lshtm.ac.uk) and Faith Green (faith.green@kcl.ac.uk) in the first instance.

REVIVED recruitment prizes

In April, May and June, we will be awarding prizes for recruitment achievements. Divaka has sent out individual targets to all recruiting sites, if those targets are met or exceeded there will be a prize for each site. This is our way of saying thank you for all of your hard work on REVIVED over this crucial time.

In addition to this all sites recruiting in a particular month will be entered into a prize draw.

The winner of April's prize draw is the **Royal Victoria Hospital in Belfast**. Congratulations, a box of chocolates is on its way to you.

The winner of May's prize draw will be announced in the next REVIVED newsletter, good luck!

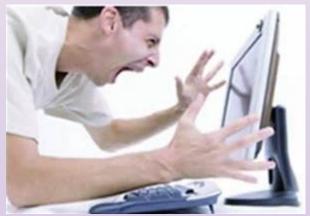


Data tips

Steve Robertson (Senior Data Manager) has put together some commonly asked questions about the REVIVED eCRF and REVIVED data:

- 1. "I can't save a form in the eCRF as the data are incomplete" A draft version of the form can be saved by waiting for 10 seconds with the form and then clicking "return to patient". A pop-up box will appear and "OK" should be clicked. When the additional data is received click to "add" the form and then "load draft". The additional data can be added and the form saved. The data is not submitted until you enter your password to save the form and will continue to appear as overdue whilst draft saved.
- 2. "I've noticed a mistake on a form that is already saved." Edits to the eCRF can only be made by a member of the CTU data management team. Please add a new query outlining the changes required and these will be made by the team.
- 3. "What point are the follow-ups measured from" All follow up times are measured from randomisation.
- 4. "Do I need to submit this SAE?" SAEs are only required for unexpected adverse events. Expected complications of PCI do not need to be reported.

All data queries should be sent to Steve in the first instance using the eCRF query system or directly by email (steven.robertson@lshtm.ac.uk).



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