REVIVED-BCIS2
Newsletter
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REVIVED

News

March has been a busy month after the Investigators Meeting. There has been one site initiation, at Liverpool on 3rd March, and there has been progress made with getting new sites on board with expressions of interest from Pinderfields Hospital in Yorkshire and The Royal Belfast Victoria Hospital.

Recruitment has been slower than expected and screening teleconferences are being planned with each site that has been initiated (those that have recruited as well as those that are yet to start recruiting). The intention of these sessions is to identify local problems and opportunities and to share experience and advice about screening.

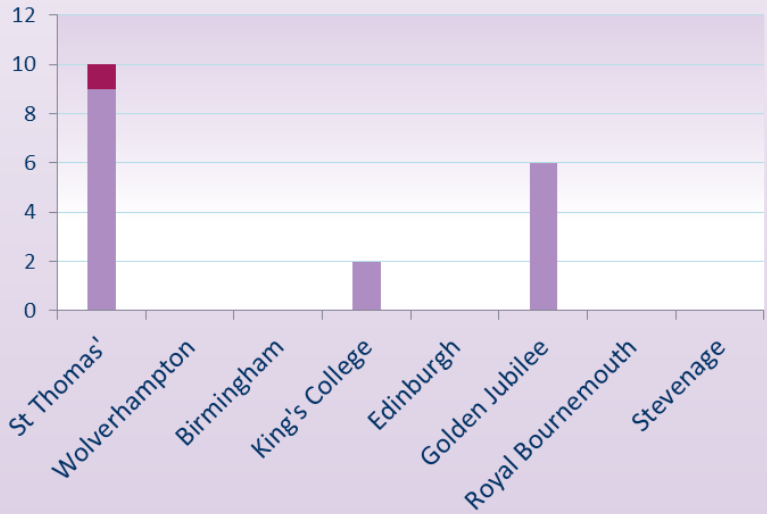
A profile on the trial was published in both the BCIS newsletter and on the BCIS website which is a great advertisement for REVIVED.

There is a detailed account of the investigators meeting on pages two and three of this expanded newsletter.

18 patients recruited

Site Progress Summary

Sites currently screening and recruiting (8)



Sites recently initiated (4):
Kettering General Hospital, Glenfield Hospital Leicester, Manchester Royal Infirmary, Liverpool Chest and Heart Hospital

Awaiting R&D approval (2):
Northern General Hospital in Sheffield, Leeds General Infirmary

Awaiting site initiation (2):
Freeman Hospital in Newcastle, James Cook Hospital in Middlesbrough

Reviewing documentation (16):

Southampton General Hospital,
Trent Cardiac Centre in Nottingham,
Queen Alexandra Hospital in Portsmouth
Royal Free Hospital in London,
Papworth Hospital in Cambridge
Royal Brompton Hospital in London
Derriford Hospital in Plymouth
Wythenshawe Hospital in Manchester
Harefield Hospital in Middlesex
Sunderland Royal Hospital
Victoria Hospital in Blackpool
Hammersmith Hospital in London
St George's Hospital in London
Pinderfields Hospital in Yorkshire
London Chest Hospital
Royal Belfast Victoria Hospital

REVIVED Investigators Meeting - 27th February 2014

Divaka Perera, chief investigator of REVIVED, started off the meeting with an overview of the trial and why it is being done. Having received ethical approval several years ago, this was a great opportunity to look back at where and why it all began. Previous trials were discussed, in particular STICH which looked at a similar patient population given CABG or medical therapy, however without stipulating that viability should be present. There was then a short talk from Matthew Lumley, a research fellow working with Divaka, on a meta-analysis they have been working on recently which underlined the need for a good quality randomised controlled trial for this question which REVIVED is addressing.

Richard Evans then gave a brief overview of the role of the CTU and an update of progress in REVIVED. Special attention was drawn to the screening log which is crucial at this early stage. Keeping the statistical talk to a minimum, Tim Clayton then presented on the importance of randomisation and why a particular number of patients is required to answer the research question. This led to further discussion about events and how important it is to capture them and report them accurately.

Roxy Senior, Professor of Clinical Cardiology and chair of the REVIVED clinical events committee, finished the first half of the day with a detailed talk on viability, which is central to the REVIVED hypothesis. Roxy stressed the importance of viability with lots of examples to illustrate.

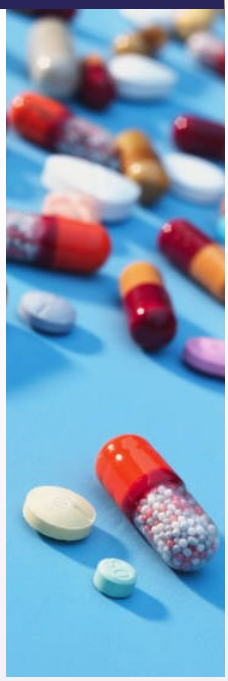
The second half of the meeting began with two opposing accounts of which treatment is best for these patients: PCI or OMT. James Cotton spoke on behalf of PCI and even as an interventionalist and advocate for PCI, he reiterated the current lack of conclusive evidence to support it as a treatment. Andrew Clark gave a very entertaining talk on the opposing argument in support of OMT which sparked a lot of debate. The mutual feeling was that there is a real need to gather good quality data to prove the argument one way or the other, which is why REVIVED is such an important trial in this area.

Sophie Jones gave a great talk about screening from the nurse's point of view with some prior input from Joanne Kelly from Golden Jubilee and Joanne Jessup at King's. She gave lots of tips on how screening works at St Thomas' and although the process may be different in other hospitals, much of it can be translated. One thing she drew attention to was the importance of having as many potential patients as possible in reserve and holding regular meetings within your REVIVED study team as there can be a long work up from identification to randomisation.

Divaka ended the meeting by going through a few case studies. Finding the right patients is one of the first hurdles in REVIVED, so this was really useful in giving everyone some background into how it has been done at St Thomas'. Divaka is happy to go through specific cases with REVIVED study teams so if there are any you are unsure about, please get in touch with the CTU in the first instance.

Many thanks to everyone for attending and contributing to a successful and inspiring meeting.

Medical therapy in REVIVED



One of the main topics of discussion at the Investigator Meeting was the optimisation of medical therapy in REVIVED patients. REVIVED is lucky to have an medical therapy committee comprising Prof Michael Marber, Prof Theresa McDonagh and Prof Aldo Rinaldi and the issues raised in the meeting were discussed among the group at length.

The OMT committee reiterated that MDT should include a heart failure specialist, which would ensure that trial patients would have been started on optimal medical and device therapy. It was agreed however that there is no need to reach the optimal doses for medical therapy prior to randomising and that the trial should reflect contemporary practice.

CRT implantation was also discussed at length, particularly improvement in LV function in the 3 months after implantation. The committee was keen not to add anything that could make recruitment more complicated (such as having to repeat echos 3 months after implantation) and were satisfied that it's unlikely that this would introduce significant bias between the two arms (PCI vs OMT) as it will have been carried out prior to randomisation. It was agreed that the time of CRT implantation will be recorded in the CRF.

Aspirin was raised as being potentially non-beneficial for heart failure and that it may even reduce the effects of ACE-inhibitors, with the suggestion that Clopidogrel is used instead for the OMT group. It was agreed that the trial should reflect current accepted practice, and that a specific antiplatelet will not be stipulated. Post-PCI therapy will be left up to the interventional cardiologist doing the case.

The medical therapy committee will continue to review available evidence annually (or in the event of relevant new data/guidelines becoming available in the interim) to ensure that drug and device therapy given to all patients in the study remains optimal and contemporary.

FAQs

Q. *Can patients with left main stem disease be enrolled in REVIVED?*

A. Yes, if successful revascularisation is likely to be achievable, the patient can be included in the trial. In fact, it is important that eligible patients with LMS disease are not excluded as this could bias the outcome of the trial.

A full list of FAQs from the investigators meeting will be available on the website soon.

Screening Logs

The recruiting sites have recently received a new screening log and screening SOP. These were updated as a result of comments at site initiations and the Investigator Meeting.

The new log is intended to be easier to complete and will enable us to make more useful inferences from the data.

Please remember to send back your receipt forms after having looked at the new screening log and read the Screening SOP version 3.

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