REVIVED-BCIS2 Newsletter Issue no.1 October 2013



News

A very warm welcome to the first edition of the monthly REVIVED-BCIS2 newsletter. These will be sent out to all of the participating sites and anyone else contributing to REVIVED. This replaces the e-bulletins you may have received in the past few months. If you would like to receive printed copies of the newsletter then please contact the team overleaf.

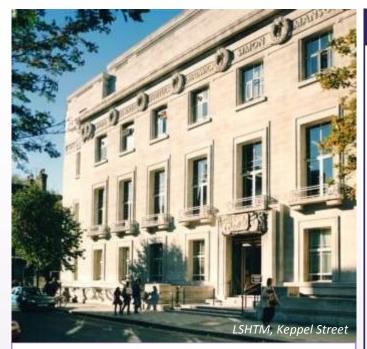
Successful site initiations have been conducted at St Thomas' Hospital in London on 1st August, New Cross Hospital in Wolverhampton on 17th September and King's College Hospital on 18th September. A site initiation is booked for the 8th October at Birmingham Heartlands Hospital. There are now 17 sites confirmed for participation in REVIVED and progress is being made with approvals and contracts at those sites. There are quite a few more sites who have expressed an interest and are currently reviewing the trial documentation.

If there is anything the Clinical Trials Unit can help with in regard to setting up the trial such as localising patient information sheets then please do not hesitate to contact us.

2 patients recruited

Participating sites





In this section we'd like to introduce various contributing members of the trial team, whether at the sites or part of the management group. As this is the first newsletter it seems only fair for the trial manager to go first.

Profiles: Richard Evans

I am the trial manager and the main point of contact for REVIVED.

I have worked here at the London School of Hygiene and Tropical Medicine Clinical Trials Unit for two and a half years, and some of you may already know me from the ERICCA trial, which I also manage. Before that I was involved in breast cancer studies here at LSHTM and worked for 6 years at Imperial College as a research coordinator on studies looking at the vasculature of the retina.

I look forward to meeting many of you on site initiations and speaking to you over the course of the trial. My number can be found below in the contact information section and I'm always very happy to talk over any aspects of the trial.

If you would like to contribute to a profile in future please get in touch.

FAQs

Device implantation

Q. Is implantation of an ICD required for the trial?

A. No. ICD therapy is recommended by both NICE and ESC guidelines for standard care. Most patients will already have an ICD implanted. If a patient is due to have an ICD implanted, it is recommended that this is before randomisation. If a patient does not have an ICD, they can still be entered into the trial.

Stress echo

Q. If a patient has had a stress echo within the past few weeks, would it be acceptable to use this for screening or would you require a separate stress echo?

A. Stress echos up to 6 months old can be used for screening. It may be an idea to get stress echo team to review stress echos with the stress echo worksheet so this can be completed easily.

Optimal medical therapy

Q. Does the patient have to be optimised on optimal medical therapy before being randomised?

A. No. Patients recruited for REVIVED should already be optimised or on the trajectory for optimisation. This is the responsibility of the treating physician and not controlled by the trial other than the OMT treatment guidelines which are provided in an SOP.

Time-scale after randomisation

Q. If a patient is randomised to PCI + OMT, how long after randomisation should the procedure occur?

A. It is recommended that the procedure take place no more than two weeks after randomisation.

Please see the REVIVED website for a list of FAQs for the REVIVED trial. As the trial progresses further FAQs will be added to the list.

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