



News

October has been a good month for trial progress with R&D approvals for King's College Hospital, New Cross Hospital, Birmingham Heartlands and Edinburgh Royal Infirmary. A site initiation is planned for the 21st November in Edinburgh.

An important amendment has now been submitted which will allow the use of MRI to assess viability, this is based on feedback from the sites on the feasibility documents and was agreed by the Trial Steering Committee at their first meeting on the 1st October. You will be informed and sent the new version of the protocol once ethics approval is received, which hopefully will not take too long.

The date of the Investigators Meeting has now been set as 27th February 2014 and you should have been contacted about this recently - remember reply slips are due back on 11th November 2013. Please get in touch if you did not receive an invitation (contact details overleaf).

2 patients recruited

Site Progress Summary

Site	Feasibility	Contract	R&D Approval	Site initiation
St Thomas'	✓	✓	✓	01/08/13
Birmingham Heartlands	✓	✓	✓	08/10/13
Royal Wolverhampton	✓	✓	✓	17/09/13
Royal Infirmary of Edinburgh	✓	In progress	✓	21/11/13
Golden Jubilee, Glasgow	✓	In progress	In progress	
King's	✓	In progress	✓	06/11/13
Sheffield	✓	In progress		
Leicester	✓	In progress		
Royal Bournemouth	✓		In progress	
Liverpool	✓			
Freeman, Newcastle	✓			
Trent Cardiac Centre	✓			
Manchester Royal Infirmary	✓			
Kettering	✓			
James Cook, Middlesbrough	✓			
Lister Hospital, Stevenage	✓			
Southampton	✓			
North Staffordshire	✓			

In this section we would like to introduce various contributing members of the trial team, whether at the sites or part of the management group.

Profiles: Divaka Perera

Divaka Perera is the Chief Investigator of REVIVED. He is an academic interventional cardiologist and so plays a dual role – a researcher by day (as a Reader in Cardiology at King's College London) and an interventional cardiologist at night (at Guy's and St Thomas' Hospital) ... and vice versa (depending on grant deadlines and PAMI calls! - Primary Angioplasty in Myocardial Infarction). The theme of his research is myocardial ischaemia in the context of coronary artery disease and valvular heart disease, with the ultimate aim of translating the insights gained from detailed physiological assessment of the heart to clinical treatments that are evaluated using carefully designed, multicentre clinical trials. Some of you would have worked with Divaka during BCIS-1, which was another UK multicentre collaborative trial conducted a few years ago under the umbrella of the British Cardiovascular Intervention Society (BCIS). We are very pleased that BCIS have officially adopted REVIVED, which is also known as BCIS-2.



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

Data Safety Monitoring Committee

The Data and Safety Monitoring Committee (DSMC) is an independent group whose role is to examine the data accumulated during the REVIVED-BCIS2 trial to ensure that it is proceeding as planned and that there are no issues surrounding patient safety. It is the only committee which has access to outcome data broken down by treatment during the trial. The DSMC meets at least annually to review the data. The meeting consists of two parts: an 'open' session where the Trial Manager updates the DSMC on recruitment, centre involvement and changes to the protocol, and a 'closed' session which involves only the DSMC and the Independent Statistician who prepares the data for review. After the meeting, the DSMC pass their recommendations for the trial to the Trial Steering Committee. Possible recommendations include to continue the trial as planned, continue with modifications or, in extreme cases, stop the trial.

The first Data Safety Monitoring Committee meeting was held on 2nd October. The chair is Peter Ludman, a cardiologist and audit lead for the British Cardiovascular Intervention Society. The other two members are Louise Brown, a statistician at the MRC Clinical Trials Unit and Suzanna Hardman, a cardiologist and Chair of the British Society for Heart failure. The DSMC is supported by Jo Dobson, the Independent Statistician at the LSHTM.

Contact information

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