



News

Congratulations to both Golden Jubilee and King's who recruited their first patients in January.

January has been a great month for trial progress with R&D approvals for Leicester, Manchester, Kettering and Stevenage. It has also been busy with site initiations at Stevenage (6th January), Sheffield (20th January) and Leicester (27th January). There are now 8 sites able to recruit.

In the last few weeks, five new hospitals have been approached: Sunderland, Blackpool, Dorset County, Royal Free and Portsmouth.

10 patients recruited

Site Progress Summary

Site	Feasibility	Contract	R&D Approval	Site initiation	Recruitment
St Thomas'	✓	✓	✓	01/08/13	6
Birmingham Heartlands	✓	✓	✓	08/10/13	Screening
Royal Wolverhampton	✓	✓	✓	17/09/13	Screening
Edinburgh	✓	✓	✓	21/11/13	Screening
Golden Jubilee, Glasgow	✓	✓	✓	21/11/13	3
King's	✓	✓	✓	06/11/13	1
Royal Bournemouth	✓	✓	✓	27/11/13	Screening
Stevenage	✓	✓	In progress	06/01/14	Screening
Sheffield	✓	✓	In progress	20/01/14	
Leicester	✓	✓	✓	27/01/14	Screening
Manchester	✓	✓	✓		
Kettering	✓	✓	✓	11/02/14	
Leeds	✓	In progress	In progress		
Liverpool	✓	In progress			
Freeman, Newcastle	✓	In progress			
Middlesbrough	✓	✓			
Brighton & Sussex	✓	✓			
UCLH	✓	In progress			
Southampton	✓	In progress			
North Staffordshire	✓				
Dorset County	✓				

ICD Implantation

It has become apparent that the guidelines for ICD implantation are not totally clear. To clarify, guidance has been provided below.

ICD implantation is not a requirement for inclusion into REVIVED.

The decision to implant an ICD is clinical and not dictated by the trial. However, if an ICD is likely to be implanted for a REVIVED patient at some point during the trial, it is requested that this occurs before randomisation.

There are many reasons why this has been suggested. There is concern that the implantation, if carried out after randomisation, will be given more readily to patients in the OMT arm. This could skew the results of the trial. Also, once randomised, if a patient is allocated to PCI, they will be put on antiplatelets. This would make an implanter very reluctant to carry out the procedure which may impact on the patient. Finally, current international guidelines recommend ICD implantation for this population, although it is understood that practically, it is difficult to keep to all guidelines.

If you are still unsure about ICD implantation and REVIVED, please do get in touch with the CTU. This will be clarified in the next version of the protocol.

FAQs

Q. What are the time restrictions on the MRI/DSE coronary angiogram and echo to determine inclusion?

A. There is no time limit for the DSE/MRI or coronary angiogram. Local MDTs will decide if the scans are still valid. However, the qualifying echo must be within 6 months of randomisation.

Screening Advice

With St Thomas' being open the longest and having the most experience of screening, Divaka has suggested his four stage filter process:

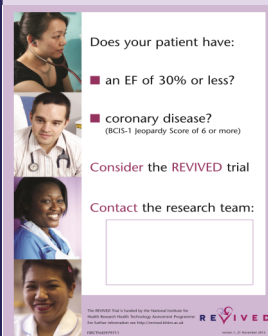
1. Check LVEF \leq 30% - there are many more patients with CAD and good LV than poor LV
2. Check coronary artery disease - exclude those with jeopardy score 4, 2 or 0
3. Check viability
4. Ensure it is possible to treat CAD by PCI to achieve complete or near complete revascularisation

In addition to this, there is an updated version of the screening SOP with detailed advice using experiences from other sites, which will be distributed in the near future.

Please remember that January's screening logs are now due back.

REVIVED Posters and Patient Cards

There are now REVIVED posters to put up in staff areas at your site to help raise awareness about the trial.



There are also patient cards which should be given to all patients randomised into REVIVED. Patients should be encouraged to carry it with them at all times and should present their card to medical staff in the event of admission to hospital. These are to help identify patients as being in the trial and provide contact details for their local REVIVED nurse.

These will be provided in files at initiation or posted out to sites who are already set up. Both the posters and cards have been approved by ethics as a minor amendment.

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