



News

June was an encouraging month for REVIVED with two new sites recruiting their first patients. Congratulations to Kaeng Lee and Alan Chung and the team at Birmingham Heartlands Hospital and to James Cotton, Emma Greatbatch, Andrew Smallwood and Stella Metherell at New Cross Hospital in Wolverhampton. Six hospitals have now recruited patients and there are positive signs at a number of other sites that recruitment will begin soon.

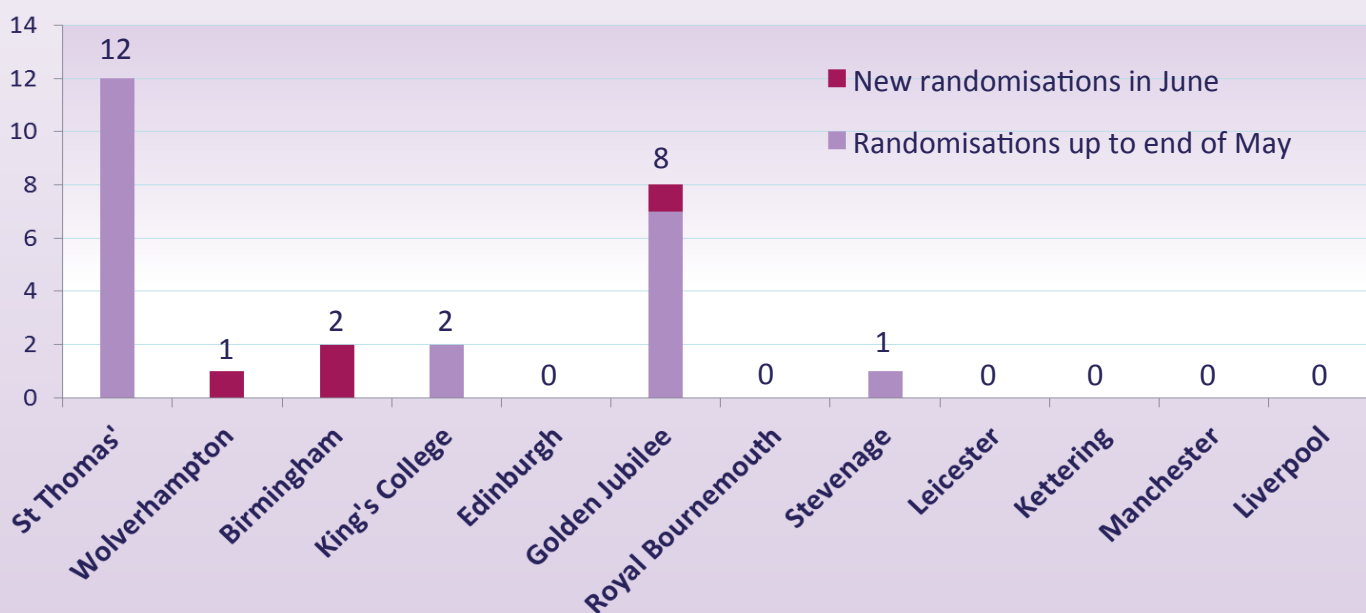
Protocol Amendment

In response to feedback from the recruiting sites, both on the screening logs and in the teleconferences held over the last two months, an amendment to the protocol has been submitted this month. Further details are on the second page of the newsletter.

Site Progress Summary

26 patients recruited

Sites currently screening and recruiting (12) arranged in order of site initiation:



Recently initiated (1):

Freeman Hospital, Newcastle

Screening but awaiting R&D approval (1):

Northern General Hospital, Sheffield

Awaiting site initiation (1):

James Cook Hospital, Middlesbrough

Reviewing documentation (16):

Southampton General Hospital
 Leeds General Infirmary
 Trent Cardiac Centre, Nottingham
 Queen Alexandra Hospital in Portsmouth
 Royal Free Hospital, London
 Papworth Hospital, Cambridge
 Pinderfields Hospital, Yorkshire
 Royal Belfast Victoria Hospital
 Royal Brompton Hospital, London

Derriford Hospital, Plymouth
 Sunderland Royal Hospital
 Harefield Hospital, Middlesex
 London Chest Hospital
 Hammersmith Hospital, London
 St George's Hospital, London
 Wythenshawe Hospital, Manchester
 Victoria Hospital, Blackpool
 Worcestershire Acute Hospitals

Protocol Amendment

A substantial protocol amendment has now been submitted to ethics for approval. The changes have been made with the aim to improve recruitment and to simplify screening which is recognised to be a complicated process. Many thanks to all of the recruiting sites who have provided their feedback in the teleconferences and provided screening data in the monthly screening logs. The following major changes may have an effect on the way screening is conducted from now on:

1. LVEF threshold increased to $\leq 35\%$

It is recommended that any patients with EF of less than 40% and extensive CAD should be highlighted in the first instance, as there is some variation in the estimate of LV function when using different modalities. These patients should then be reviewed with the PI.

2. Viability threshold changed to 4 or more segments that can be revascularised by PCI, and all viability modalities can be used

This change is being made to make viability assessments simpler, as well as allowing sites that have prohibitively long DSE or MRI waiting lists to use their local viability assessments.

New promotional materials have also been submitted, which was something highlighted by the recruiting sites. The main poster has been updated and a further three have been produced to help keep awareness of REVIVED high at your hospital. A leaflet has also been designed which is intended to give an overview of the trial and also contains some case studies. The leaflet will be a useful resource to send to referring centres, as this was also highlighted at the teleconferences as a potential source of patients that is underutilised at present.

Approval for this amendment is expected within the next month so it is recommended that the new criteria is considered from now on. For open sites, once approved it may be useful to go through old screening data to see if there were any previously excluded patients with an EF in the 30-35% range or that marginally missed out on eligibility due to the viability criteria. Versions of the new trial documents will be distributed to open sites shortly after approval for their local R&D review.

In addition the CRF will be amended to reflect the changes above and to simplify some of the data capture.

Further information about the changes will be sent once REC have given approval, which is expected in the next few weeks.

Introducing Matthew Lumley

A warm welcome to Dr Matthew Lumley who has joined REVIVED to actively support the day to day running of the trial particularly with respect to clinical questions that arise during the screening and recruitment of patients.

Matthew is a Cardiology Registrar, BHF Clinical Research Training Fellow and PhD Candidate at Kings College London. His primary area of research is ventricular-valvular-coronary coupling in aortic valve stenosis. Alongside Matthew's keen interest in physiology, he has a long-standing interest in clinical trial design/methodology and medical statistics.



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