



News

June has been a great month for REVIVED with 8 patients randomised. This includes the first patient from Northern General Hospital, Sheffield. Congratulations to Julian, Abdallah, Joyce and the rest of the team. Congratulations also go to the team at St Thomas' who recruited three patients this month. Worthing Hospital and Belfast Victoria Hospital gained R&D approval in June and site initiations are being planned for both.

Sites have been busy implementing the latest amendment, and more information is on page 2 in regards to changes. It is now over 35 days since the amendment was approved so it can be implemented at all sites, unless your R&D has asked for more time to review.

LUCKY NUMBER

Unfortunately there was no winner for the lucky number in June.

This month's lucky number is 105

Whichever site recruits the 105th patient over the course of July will win a box of chocolates. Good luck.

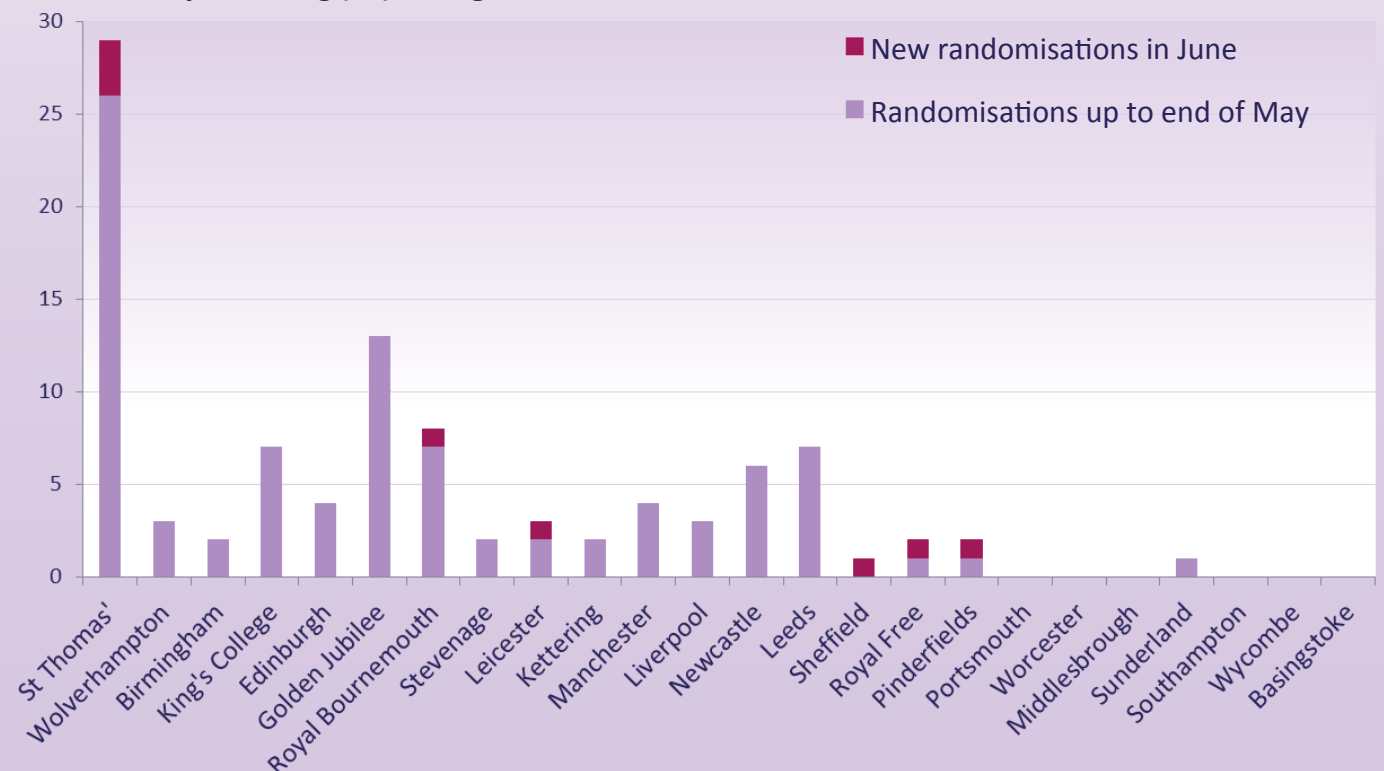
CRF Version 4

There is now a new version of the CRF in use. Version 4 has been issued to reflect the changes in the new protocol, Version 7. The eCRF will be updated in the next few weeks. Printed copies of the CRF are available on request.

Site Progress Summary

99 patients recruited

Sites currently screening (24) arranged in order of site initiation:



Amendment 8 Case Study

To help put the amendment into context, an example case has been created to show how the changes could make recruitment easier.

Patient 5 was identified in a heart failure clinic and was then referred onto the REVIVED team as a potential for the trial. They had undergone an MRI 6 months ago which showed an EF of 27%.

Under the old protocol, a new echo would have been required to assess eligibility.



The nurse reviewed the notes and medical history of patient 5 and saw that all required tests had already been done. The patient was discussed with the PI at their fortnightly meeting and was determined to be eligible. The patient was assessed as needing an ICD and this was scheduled for 3 weeks time. The patient information was given and informed consent was sought. Patient 5 was randomised to PCI+OMT the next day. The PCI was to be arranged after the ICD had been implanted.

Under the old protocol, randomisation would have been required to be postponed until a potential PCI date within 30 days of randomisation had been arranged.

In this patient the process was sped up both by not having to wait for a new echo to be done to assess eligibility and by not having to wait for an arranged PCI date. This example highlights two stages at which the amendment has improved the patient pathway into REVIVED. For more information, contact rebecca.matthews@lshtm.ac.uk

ICD guidance

ICD guidance has been updated in the new protocol, version 7. The most important factor in the decision to implant is that the local guidance at site is followed. This means that if local protocol dictates that ICDs are not implanted where PCI is planned, this should be followed. Although this may mean a higher proportion of ICDs are implanted after randomisation and/or PCI, as long as the implantation is recorded in the CRF, this will cause no problems.

Additionally, if ICD implantation is planned before randomisation, there is no need to reassess the patient (e.g. LVEF) after the device has been put in, to see if their situation has improved.



Screening log notice

As you know, screening logs are not collected every month but at snapshots twice a year. To avoid any popular holiday periods that may affect screening, it has been agreed that these will be collected in November and May. Screening snapshots will involve filling in a full screening log for that month and electronic templates will be sent out closer to the time.

The first snapshot will be in November 2015. Reminders and further details will be sent out in September.

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This project was funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme (project number 10/57/67).


National Institute for
Health Research

ISRCTN45979711 / NCT 01920048