



News

March has been a busy month for REVIVED with two successful regional meetings held in Leeds and London. We were delighted that 48 staff attended and 20 different hospitals were represented. It was an opportunity for everyone to give feedback on the trial so far and to discuss changes to the protocol that would make recruitment easier. See pages two and three for more details. A big thank you to all the attendees and speakers at both meetings and Rebecca Chu, Trials Assistant at LSHTM for her work in organising them.

There were two successful site initiations: James Cook Hospital, Middlesbrough on 13th March and Sunderland Royal Infirmary on 20th March. A warm welcome to those new sites.

Last but not least, fantastic news from the team at Leicester who recruited their first patient this month. Congratulations to Iain Squire, Tony Gershlick, Kris Kenmuir-Hogg, Gerry McCann, Gail Richardson and the rest of the team.

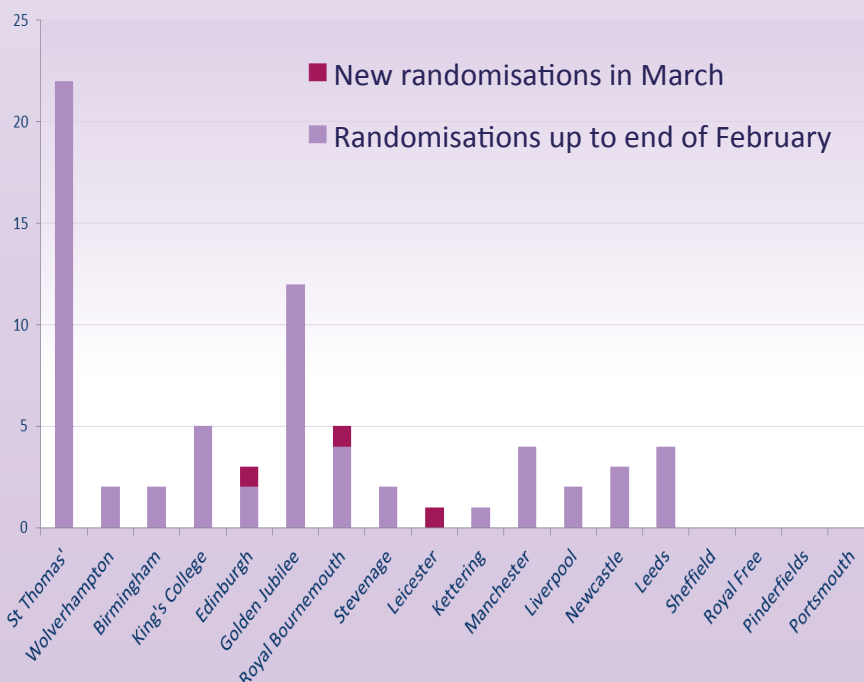
LUCKY NUMBER

April will be the inaugural month of the REVIVED Lucky Number competition. The site that recruits patient number **74** this month will receive a box of chocolates. Good luck!

Site Progress Summary

68 patients recruited

Sites currently screening (18) arranged in order of site initiation:



Easter Closure

The Clinical Trials Unit at LSHTM will be closed from Friday 3rd April and will reopen on Wednesday 8th April 2015.

Please refer to the website for FAQs. If you have any urgent clinical queries regarding the trial during this time, please contact Divaka Perera by email at: divaka.perera@kcl.ac.uk.

Most important have a relaxing and enjoyable Easter!



Staying REVIVED at Leeds General Infirmary—18th March

Firstly, a big thank you goes to the team at Leeds for hosting this meeting and to **John Greenwood, PI at Leeds General Infirmary** for chairing the meeting. John started off the meeting with an introduction into what the meetings were all about: listening to the sites to understand what issues are present and talking about what can be done about them.

John Greenwood and Divaka Perera, Chief Investigator both presented some REVIVED cases which sparked some interesting discussions. Divaka's cases are available on the REVIVED website: <http://revived.LSHTM.ac.uk/case-studies/>

Nurses Perspectives

Manchester Royal Infirmary and Leeds General Infirmary

Sarah Evans, Trial Coordinator at Manchester Royal Infirmary spoke about their method of recruiting patients. This gave great insight into how their team works.

1. Screening starts by looking at all the uploaded echo reports for patients with an EF less than 35%. This is done once a week by the trial coordinator and trial administrator.
2. The trial coordinator and nuclear medicine consultant then check to see if they have had a viability test (PET scan at Manchester).
3. The research nurses then check the patients history. This includes date of angio, medication and other inclusion/exclusion criteria.
4. Dr Mamas (PI) and Dr Fraser (Co-I) then review the angiogram to determine suitability for revascularisation.
5. The patient is then contacted by phone before being sent a PIS and being brought in at their next clinic appointment for consent.

Kathryn Somers, Research Nurse at Leeds General Infirmary then spoke about their method of recruiting patients. The Leeds team have put a lot of time into increasing awareness within the hospital with posters and training sessions. The screening sources used are: wards, local cardiology database, attending the weekly MDT, stress echo list and reports and clinical referrals (both interventional and heart failure). Some of the main challenges that the team have come across are time, complex procedures (e.g. CTOs), waiting lists for EP review and echo and finding patients despite best effort.

Although these methods may not be transferable to all other sites, it really shows the variation in screening techniques around the country.

Some of the key points that came out from these talks was how REVIVED really is a team effort and how regular meetings are important to keeping patients moving through the process. It is also clear that a huge amount of work has gone into REVIVED and that the numbers randomised do not tell the whole story.

LV function on PCI outcomes

Mamas Mamas, PI at Manchester Royal Infirmary gave a very interesting talk on the impact of LV function on PCI outcomes.

He also strengthened the point that it is not known whether PCI or OMT is better for patients, which is exactly why the REVIVED trial is so important.



Leeds General Infirmary

Staying REVIVED at Guy's Hospital, London—26th March

Nurses Perspectives

Royal Bournemouth, St Thomas' and King's College Hospitals

The second Staying REVIVED meeting was held on the 16th Floor of Guy's Hospital, which has incredible views across London. Thank you to **Divaka Perera** for chairing the meeting, and to the speakers.



Guy's Hospital

Peter O'Kane presented a few slides prepared by the Bournemouth nursing team. They screen from clinics, wards and cath labs. From those, cath labs have been seen as the most fruitful. They also identified communication is key and presenting the trial to the patient in the right way. Referrals from Poole form a significant proportion of screened patients (about 25%). The Bournemouth Co-Investigator, Christopher Boos is based at Poole.

Sophie Jones, Research Nurse at St Thomas' presented an overview of how things are run at St Thomas'. Sophie reported that their recruited patients have come from; JCC (50%), Clinic (18%), cath labs (14%), Direct referral from DGHs (14%) and HF database (5%).

Around 60% of patients have been identified after having an acute event with a new diagnosis of heart failure. For patients not recruited the main reasons are inadequate viability (20%), patient declined (5%) and EF was too high on a later echo (10%). The main cause of delay is waiting for ICDs to be implanted.

Jonathan Breeze, Research Nurse at King's presented on how patients are identified at King's. They screen all inpatients, all HF outpatients, JCC, HF MDM, CRT/ICD clinic and have referrals from PRUH.

What support can the CRN give?

Gaye Hadfield, South London CRN explained the CRN system of embedded staff and flexible staff and how money is allocated to each trust. Some funding is based on recruitment targets set by the site. If target recruitment is set too low funding can be reduced.

If sites are experiencing difficulties with CRN funding, Gaye kindly offered to identify local Research Delivery Managers and liaise with other trusts to see what can be done. The first step is to get in touch with Gaye at: Gaye.Hadfield@gstt.nhs.uk.

Biomarkers and Ischaemic Cardiomyopathy

Theresa McDonagh, Co-Investigator at King's College Hospital presented on biomarkers in heart failure and her proposal for a substudy. The two biomarkers that would be focussed on are Galectin 3 and ST2 both of which are associated with fibrosis. This is relevant in this population as ischaemia tends to lead to fibrosis. BNP is a more routinely used biomarker for heart failure however it has greater variability than both Galectin 3 and ST2. Troponin could be explored but is not specific enough. Anecdotally, Theresa commented that she had not seen a patient recently with heart failure that did not have a raised high sensitivity troponin.

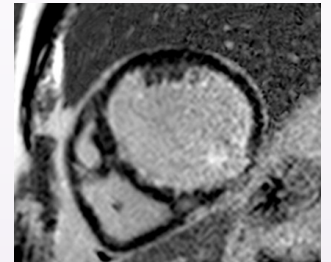
Staying REVIVED at Guy's Hospital, London—26th March (cont.)

Case Studies

Case studies were presented by **Andrew Cai at King's College Hospital**, **Peter O'Kane, PI at Royal Bournemouth**, **Natalia Briceno, research fellow at St Thomas'** and **Gerry Carr-White, Co-Investigator at St Thomas'**.

Andrew Cai showed two cases that did not go into REVIVED. It was noted that patients seen at the heart failure MDT and JCC may have different outcomes. The JCC has many individuals present (surgeons and interventionalists) all of whom often have different ideas for how the patient should be treated.

Peter O'Kane showed the five cases that they have randomised to REVIVED and two that were not. One of the main messages from Peter's presentation was that it is important to have colleagues on board for REVIVED to be a success.



Natalia and Gerry finished off the day with two cases from St Thomas'.

Staying REVIVED

General comments from both meetings

- Chronic stable patients may be more likely to refuse participation in the trial than those with a new diagnosis.
- Colleagues are not always initially on board with REVIVED. This may be improved by engaging them more in the trial and presenting and promoting the trial. Please let us know if we can help with this in any way.
- ICD implantation is still an issue at some sites. Colleagues will want to wait to see what the patient is randomised to before deciding to put in a device.
- Attention was drawn to the ISCHAEMIA trial. One of the main eligibility criteria for this trial is that patients must have an EF greater than 35%. If sites are participating in both trials, screening could be partially combined.

Potential protocol changes

The following are potential protocol changes. Some were planned and some have come about from the regional meetings.

- Simplification of inclusion and exclusion criteria
 - Removal of jeopardy score
 - Removal of angina exclusion
 - LV function for eligibility can be determined by echo or MRI within 1 year, however if an echo less than 6 months old is not available a baseline echo should be taken
- No time limit from randomisation to completion of PCI
- Removal of 30 day follow up
- Removal of need for formal MDT (still requiring input from heart failure, interventionalist and imaging specialists)

Contact information

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**National Institute for
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