REDDS2

MONASH University

Radboudumc university medical center

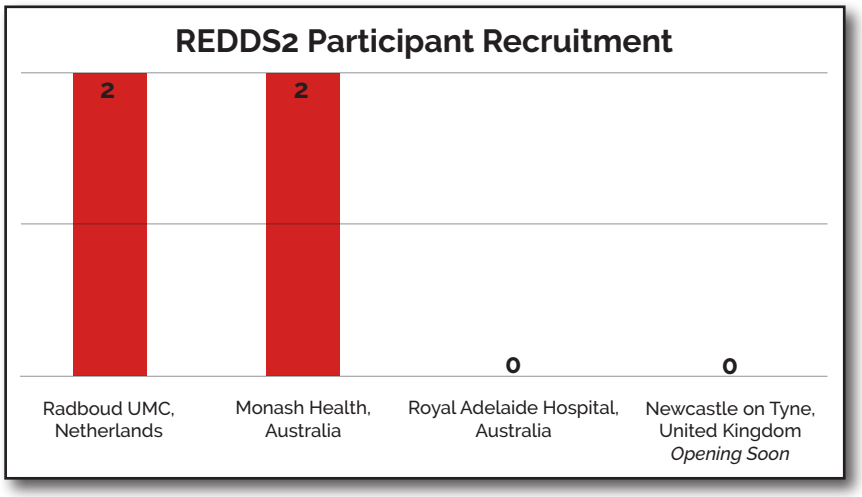
NHS The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue 1

A Randomised Feasibility n-of-1 Trial of Weekly-Interval Red Cell Transfusion in Myelodysplastic Syndromes

July 2021

Sites open to recruitment and current recruitment numbers. Target recruitment is 30 participants.



Despite some delays due to the COVID-19 pandemic our trials units have been able to keep the project moving across the globe. We are pleased to announce that Newcastle upon Tyne Hospital will opening to recruitment in the coming months.

Thank you to everyone for all the work that has helped the project continue during some very difficult times.

We will be adding additional sites across the United Kingdom in the months ahead.

Pictured above are Dorothea Evers, Marlijn Hoeks and Annegeet van den Bos from our Dutch trial team. Dorothea is holding the first unit of matched blood for their first participant.

MEET THE TEAM

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GENEActiv accelerometers are being used to capture physical activity, measured by steps per day, pre-and post-transfusion of the participants while they are on the trial. These devices provide an objective quantitative measurement for daily physical activity and are associated with stronger correlations with clinical outcomes compared to self-reporting of physical activity via questionnaires. The devices should be worn on the participant's non-dominant hand for three weeks in each arm of the study, including while they sleep

Jamar Plus+ Digital Hand Dynamometer

Sarcopenia is associated with impaired QoL, disability, increased mortality and prolonged hospitalisations. In the European consensus guideline on sarcopenia assessment, handgrip strength is the only recommended test. Older adults with anaemia have poorer handgrip strength however the effect of transfusion is unknown. Handgrip strength is measured quantitatively using a hand dynamometer, and will be performed using a Jamar Plus Digital Hand Dynamometer according to a recently proposed standardised approach.

Why REDDS2??

-Establish the feasibility of delivering weekly red cell transfusions using matched red cells rather than waiting for results of contemporaneous cross-matching.

-Determine the appropriate tools to measure the impact of variation in transfusion frequency on patients' health-related QoL and physical function, including a primary outcome to be measured in a definitive trial.

-Develop the intervention protocol for a trial for red cells transfusion. The ultimate goal is to undertake a definitive phase III randomised trial to compare different strategies for red cells transfusion in patients with transfusion-dependent MDS.

-Explore patient and staff experiences of the new weekly transfusion schedule including: potential enablers, barriers, positive and negative experiences, acceptability and comparison to the standard transfusion schedule. This will provide greater in-depth understanding of the weekly transfusion schedule and provide information to develop future clinical transfusion trials.

PROTOCOL 6.0 *COMING SOON*

Protocol Version 6.0 dated 21 May 2021 has been submitted to Monash HREC. We will send around the approval once received.

Some of the changes include:

- A time window for iron biomarker collections is now 2-3 hours pre- and post-transfusion.
- Increased timeframe for capturing SAEs to 30 days following the end of trial treatment.
- Specified that CTCAE version 5 dated 27 November 2017 will be used to grade adverse events.
- Reporting adverse reactions related to red cell transfusions including IV related issues.
- Newcastle Upon Tyne (NUTH) will now be the UK sponsor.
- Now includes a printable version of the Borg scale for 6MWT
- Handgrip strength guidelines updated for the Jamar Plus digital dynamometer.

For questions or comments on the trial or this newsletter, please contact your local REDDS2 team or:
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