

Newsletter

August & September 2023, Issue 18 & 19

Achievements

Thank you to:

Kent and Canterbury Hospital,
Nottingham City Hospital &
University Hospitals Dorset NHS FT
for registering 1 patient to the
trial each over the last couple of
months!

Well done to Kent and Canterbury
Hospital for randomising a
patient!

A huge thank you to all the site teams for their support to the trial so far!

Welcome to **The Rotherham NHS Foundation Trust** who opened to recruitment in October!

Recruitment Update

32 Participants Registered17 Participants Randomised20 Sites Open to Recruitment

ONLY 3 RANDOMISATIONS

until we reach the target of 20 patients randomised for Safety Analysis.

CAN YOU HELP US REACH THIS MILESTONE?

NEW Patient Diaries

Have you received the NEW Patient Diaries for the trial?

The patient diaries were updated to make it easier for patients and research teams to complete as part of the implementation of Substantial Amendment 04.

The **NEW** Patient Diary (V3.0 08Mar2023) consists of an A5 folder and a series of fortnightly and monthly cards. The Diary Folder is for the patient to store their current Diary Card in between visits while the individual Diary Card details the current dosing regimen and includes a space for the patient to record how much and when they have taken IMP.

The Patient Diary Site Guide (V1.0) provides support on how to use the new patient diaries and will be available for download from the electronic Investigator and Pharmacy Site Files soon. The guide is also attached to the newsletter mail out.



The diaries and ID cards have been posted to sites in September, please let us know if you have not received these.

To request more diaries, please email the team via <u>repairMDS@warwick.ac.uk</u>

Upcoming CRF Clinics

We are happy to announce we will continue with our monthly 30-minute online sessions focusing on CRF completion tips and database training. Registration details for the next session below:

11:00–11:30 Monday 23rd October: Screening Log Overview

Register here:

https://events.teams.microsoft.com/event/2777 a168-84b0-4846-9a5d-

<u>da9a5d885265@09bacfbd-47ef-4465-9265-</u> 3546f2eaf6bc





Past session's materials and recording can be accessed via the trial website here:

https://warwick.ac.uk/fac/sci/med/research/ctu/trials/repairmds/health/crfclinics/

Sharing Prescriptions with REPAIR-MDS

When sending redacted prescriptions to the Central Trial Team please do so via a secure method by utilising local encryption, password protecting the document (if sending via email) or OneDrive.

We are in the process of arranging transfer via OneDrive, and/or Microsoft Teams channel. Please contact the Central Team for support if required.

REMEMBER: When redacting PDF documents, please ensure that any redaction is **irreversible** by either locking the document when saving or using PDF programme redaction features.

Understanding Patient Withdrawal

If a patient decides to withdraw from trial there are currently **three levels of withdrawal** the patient can choose between. Below is a quick guide of which trial activities we would expect to cease and carry on.

The withdrawal process is currently under review and any updates will communicated to sites directly

Withdrawal Options	Trial Treatment	Samples for Science Collection	Scheduled Clinic Visits
A. Cease trial treatment but remains in follow-up and WILL provide samples	X		
B. Cease trial treatment but remains in follow-up and <u>WILL NOT</u> provide samples	X	X	
C. Withdraw from the trial completely and will not be followed up	X	X	X

Recruitment Update



We are so proud to be working with so many fantastic research teams across the UK!

We know that participant recruitment to REPAIR-MDS can be challenging but we would like to recognise the hard work all teams have put in so far and your continued support of the trial!

Well done and thank you to our top recruiting sites!

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REPAIR-MDS Site	Date Opened to Recruitment	Participants Registered	Participants Randomised
Russell's Hall Hospital	21-Dec-21	4	3
Kent and Canterbury Hospital	21-Apr-22	4 NEW	2 NE
University Hospital College London	11-Mar-22	3	2
University Hospitals Birmingham Foundation Trust, Good Hope Hospital	12-Oct-22	3	2
Hull University Teaching Hospitals NHS Trust, Castle Hill Hospital	niversity Teaching Hospitals NHS Trust, Castle Hill Hospital		2
Royal Cornwall Hospital NHS Trust	02-Sep-22	3	2
King's College Hospital NHS Foundation Trust	12-Apr-22	3	2
Aneurin Bevan University Health Board, Royal Gwent Hospital	30-Jun-22	2	1
University Hospitals Birmingham Foundation Trust, Heartlands Hospital	12-Oct-22	1	1
University Hospitals of Leicester NHS Trust	08-Dec-22	2	0
Nottingham City Hospital, Nottingham University Hospitals NHS Trust	31-Jul-23	1	0
Colchester General Hospital, East Suffolk & North Essex NHS FT	11-Aug-22	1 NEW	0
Basingstoke and North Hampshire Hospital	05-Jun-23	1	0
James Paget Hospital	04-Jul-23	1 NEW	0
University Hospitals Dorset NHS FT	17-Jul-23	¹ NEW	0
Royal Hampshire County Hospital	31-May-23	0	0
South Tees Hospitals NHS Foundation Trust	04-Jan-23	0	0
Mid & South Essex NHS Foundation Trust, Broomfield Hospital	22-Nov-22	0	0
Grampian Health Board, Aberdeen Royal Infirmary	29-Mar-22	0	0
TOTAL		32	17