

REPAIR-MDS Newsletter

June 2022, Issue 04

June Achievements

Russell's Hall Hospital has had their first monitoring visit! This visit went well and we thank you for the warm welcome!

Russell's Hall Hospital also randomised their 3rd participant! Well done for hitting your annual recruitment target within 6 months!

Aneurin Bevan University Board is open to recruitment as of this month! Welcome aboard!



Get your posters

Our team has developed two posters aimed at clinicians to raise awareness of the trial. These posters can be shared with referring or feeder hospitals to support recruitment, as well as in your staff spaces.

Please email repairMDS@warwick.ac.uk to arrange posters to be sent to you or your partner hospitals.

Does your clinic have any patients who have:

- Suspected or diagnosed **very low, low or intermediate risk MDS**
- An IPSS-R score of 3.5 or below
- Failed, or predicted not to respond to ESAs?

If so they may be eligible to join **REPAIR MDS**

Reposured drugs to improve haematological responses in Myelodysplastic Syndromes

REPAIR-MDS is an open label phase II randomised trial evaluating haematological improvement in **low-risk MDS** patients by comparing VBaP and Danazol.

Scan the QR code to see the full trial inclusion/exclusion criteria and learn more about the trial.

Suitable patients can be referred to the Haematology team at:

For any queries, contact our Trial Coordinating team on: repairMDS@warwick.ac.uk

Co-Sponsors: The Dudley Group NHS Foundation Trust & University of Warwick, WARWICK The Dudley Group NHS Foundation Trust, NHS Blood Cancer UK

REPAIR MDS

Reposured drugs to improve haematological responses in Myelodysplastic Syndromes

IPSS 10010203 | IPSS-CTN 112012024

An open label phase II randomised trial evaluating haematological improvement in **low-risk MDS** patients by comparing VBaP and Danazol.

Who is Eligible?

Patients who are deemed very low, low or intermediate risk MDS and who have an IPSS-R score of less than or equal to 3.5, and who have failed ESAs treatment, become ESAs refractory or are unlikely to respond.

What is the Treatment?

- An oral drug regime where the dose increases/ titrates over several weeks
- Patients will be randomly allocated to either:
 - Danazol therapy arm
 - OR
 - VBaP therapy arm

Targets

- 120 participants
- 20-30 sites across the UK

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REPAIR MDS

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Website: [REPAIR MDS \(warwick.ac.uk\)](http://REPAIR MDS (warwick.ac.uk))

Pill Counts - How-To Guide



The Pill Count data is really important for us so we can check if the patient is taking the trial medication correctly.

STEP 1

Count how many tablets the patient brought with them and record in the CRF and medical notes.

These are the **tablets remaining**.

TOP TIPS:

- Choose a quiet place
- Use a counting triangle
- Encourage patients to bring back empty blister trays and packs

STEP 3

Check the tablets taken match the:

1. Patient Diary entries
2. Expected no. of tablets taken as per prescription

Record any **missed or extra doses** identified by the pill count or patient diary in the CRF.

STEP 5

Explain the dose they should be taking until next visit and remind the patient to bring all trial medication back to next clinic visit

Not adding up?

Speak to PI and Pharmacy to investigate.

Is medication being held for this patient elsewhere?

Medication should not routinely be held at site after being dispensed/given to patient. If it is deemed necessary to hold stock for the patient between visits this must be clearly documented.

Report/ highlight any issues to the central trial team immediately!

STEP 2

Calculate the **tablets taken** by:
no. of tablets at last visit (remaining + dispensed) minus no of tablets remaining today.
Record in the CRF and medical notes.

STEP 4

Ask the patient how they are getting on with the trial treatment. Will the patient have enough medication until you see them again or will they need a further dispense?

We value your feedback

We can not do research without you and that is why we value your feedback!
Please let us know if the trial processes are working for you and whether you have any suggestions for us by emailing repairMDS@warwick.ac.uk