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Patient Information Sheet

Title	Red blood cell transfusion in Myelodysplastic Syndromes 2 (REDDS2): A randomised n-of-1 feasibility trial of weekly-interval red cell transfusion in myelodysplastic syndromes
Short Title	REDDS2
Principal Investigator:	**INSERT LOCAL INFORMATION**
Site:	**INSERT LOCAL INFORMATION**

Invitation and brief summary

You are invited to take part in a research trial. Please read the following information carefully to help you decide if you want to take part. We would like you to understand why we are doing this research and what it means for you. You will be given the opportunity to discuss this study further with a study contact, relative, friend, or your GP and ask any questions. Please ask us if there is anything you are not clear on.
REDDS2 is a research trial. It aims to test whether giving weekly blood transfusions to maintain stable Haemoglobin (Hb) will work for you. You are invited to take part in this study as you have a Myelodysplastic Syndrome (MDS) and receive regular blood transfusions.

Participation in this research project is entirely voluntary. Your standard of care will not be affected, should you wish not to take part. By signing and dating the consent form you are agreeing that you have: understood what you have read; consent to take part in the research project, consent to the test and treatments that are described and consent to the use of your personal information as described in the Participant Information Sheet.

You will be given a copy of the Participant Information Sheet and consent form to keep.

What is the purpose of the research?

Patients with Myelodysplastic Syndromes (MDS) are currently receiving transfusion care by Red Blood Cell transfusions that are typically 2-4 units every 3-4 weeks. The purpose of this study is to compare your usual transfusion schedule against a new weekly transfusion schedule using matched red blood cells. It is possible that another strategy of lower doses and weekly transfusions of red cells is more effective and acceptable than the current standard of transfusion care.

We need to compare different treatments and their results to see which one is better by comparing your usual transfusion schedule (Arm A) with a weekly transfusion schedule (Arm B). Both schedules will be personalised for your individual requirements, as each patient with MDS is different and has different transfusion needs. All participants will receive both treatment arms. You will be randomly started in either Arm A or Arm B. After 6 weeks, you will switch to the other arm.

There are two parts to this research project:

Part 1 – will compare your usual transfusion schedule to a personalised weekly transfusion schedule.

Part 2 – is an optional 30-45 minute interview to discuss and explore your experiences with the different transfusion schedule. A separate Participant Information Sheet and Informed Consent Form will be given to you if you wish to participate in this part of the study.

What will taking part involve?

If you decide to participate in this research project, your consent will be obtained and you will be asked to sign an Informed Consent Form. Your MDS type will be recorded along with other medical history and any recent blood results. You will be randomly started in either Arm A or Arm B. After 6 weeks, you will switch to the other arm.

In Arm A you will receive transfusions as per your usual transfusion schedule over a 6 week period and directed by your usual treating doctor.

In Arm B you will receive weekly transfusions over a 6 week period. The number of red cell blood units is based on your usual transfusion schedule and will be reviewed and approved by your treating doctor. You will receive units of blood that are closely matched to your blood type, to reduce the risk of your body forming antibodies against them.

It is important to tell your study doctor/nurse about any treatments or medications you may be taking, including over-the-counter medication, vitamins or herbal remedies, acupuncture or other alternative treatments whilst participating in this study. You should inform your doctor/nurse of any changes to these during you participation.

At the end of the study you will return to your usual clinic visits and blood transfusions.

What will happen to me if I take part?

You will be in the study for 12 weeks, during which you will need to come to the see the study team every 3 weeks for study visits. During the visits the study doctor will ask you about your health do a basic examination and also check your blood results. While on your normal transfusion regime, the number of clinic visits and transfusion visits is unlikely to be increased. On the weekly arm you will attend for a transfusion on the day unit each week but we are aiming for these visits to be complete within 2-3 hours.

At each study visit a routine blood sample will be carried out to check your blood counts and for transfusion testing. In addition, 5ml of blood (approximately one teaspoon) will be taken to measure your iron levels at 3 visits: the beginning of the trial, once in Arm A (before and 2 hours after transfusion) and once in Arm B (before and 2 hours after transfusion).

The doctor/research nurse will give you four short questionnaires asking about you and your health. A copy of these questionnaires is available if you wish to look at them prior to taking part.

You will also be asked to do a six-minute walking test (which checks how far you can walk on flat ground for six minutes) and also a handgrip strength test which checks how strong your handgrip is. You will also be given a wrist-worn device (like a Fitbit) during the trial, to measure your physical

activity, the wrist-worn device will be provided to you at the beginning of the study and will be returned when you reach your final study visit.

When you visit for a transfusion appointment, you will have routine transfusion-related tests such as: blood count, blood group and testing for antibodies. Your Hb level will be monitored during the trial and recorded on the study form, but you will not be told what the result is - this is called 'blinding' and allows more accurate assessing of the study results.

After the research is completed you will receive a phone call within 3 months of your trial treatment finishing. During the call there will be a short interview with a researcher to ask about your experience. Your most recent routine blood tests will also be checked for your Hb and transfusion-related tests.

At the end of the 12-week study period, you will return to your usual doctor for ongoing treatment. As you will have experienced both Arm A and Arm B, you can discuss with your doctor which treatment you prefer and continue on that treatment if desired.

At the end of the study, if you would like to see a summary of the results from all the patients who took part, you can ask the doctor/nurse to contact you when the information is available.

There are no additional costs for taking part in this research project, nor will you be paid. If you are asked to travel for extra visits your expenses will be covered.

Your local doctor/GP will be told of your decision to participate in this study by the local study team via GP letter.

Extra Blood samples (optional)

You will be asked if you are willing to give additional consent concerning your blood samples during the study. These blood samples are optional. If you are happy to provide these optional, extra bloods you will be asked to sign an Informed Consent Form specific to the extra bloods. These blood samples will be tested for special markers of iron metabolism and inflammation to see if more frequent blood transfusion has effects on either iron levels or inflammation.

These samples will be given a code which will be unique to you. The samples will not have your name or date of birth recorded on. The samples will be stored for the duration of the study at Newcastle Central Biobank in accordance with their Standard Operating Procedures and under the Human Tissue Act. The samples will be destroyed at the completion of the study under the Human Tissue Act.

Do I have to take part in this research project?

Taking part in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any time.

If new information becomes available about the treatment during the study, your study doctor will inform you of this and discuss whether you wish to continue in the study. If you decide to withdraw, your study doctor will arrange for your regular healthcare to continue. If you decide to continue in

the study you will be asked to sign an updated Informed Consent Form. Also, on receiving new information your doctor might consider it to be in your best interests that you withdraw from the study. Should this happen your doctor will explain the reasons and arrange for your regular healthcare to continue.

What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team. No additional personal information will be collected from you. You should be aware that data collected by the project up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

Will my GP be told about my involvement in this trial?

Yes, we will send a letter to your GP informing them that you are participating in this study along with a summary of the study and what it involves. By signing the Informed Consent you are confirming you are happy for your GP to be informed.

What will happen to my information?

By signing the Informed Consent Form you consent to the study doctor and research staff collecting and using your personal information for the research project. A copy of your consent form will be sent to The Newcastle upon Tyne Hospitals NHS Foundation Trust to check it has been completed correctly. This will be transferred from the hospital to The Newcastle upon Tyne Hospitals NHS Foundation Trust using secured methods.

How will we use information about you?

We will need to use information from you from your medical records for this research project.

This information will include you're:

- Initials
- NHS number
- Name
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be sent to Australia. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from your local research team
- by asking a member of the research team

What will happen to the results of the research trial?

We expect that the results of this research project will be published and/or presented in a variety of ways. In any publication and/or presentation, researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

Who has reviewed the research project?

All research in the United Kingdom involving humans is reviewed by an independent group of people called the Research Ethics Committee (REC). The ethical aspect of this research project has been approved by the REC within the United Kingdom.

What if something goes wrong?

If you have a concern about any aspect of the trial please contact your local doctor (see contact details below). Alternatively, you can contact one for the researchers running this trial and discuss concerns.

Your local contact people for the trial are:
Contact details for Principle Investigator: INSERT LOCAL INFORMATION

Contact details for complaints: INSERT LOCAL INFORMATION

If you are unhappy and wish to complain formally and confidentially you can do this through the NHS complaints procedure by speaking to a member of the PALS (Patient Advice and Liaison Service) on (INSERT LOCAL PALS INFORMATION

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Thank you for taking time to read this information sheet.

Informed Consent Form

Title Red blood cell transfusion in Myelodysplastic Syndromes 2 (REDDS2): A randomised n-of-1 feasibility trial of weekly-interval red cell transfusion in myelodysplastic syndromes

Short Title REDDS2

Principal Investigator: **INSERT LOCAL INFORMATION**

Site: **INSERT LOCAL INFORMATION**

Declaration by participant

	Please initial the box only
I confirm that I have read the information sheet dated …… (Version……) for the study above. I have had the opportunity to consider the information, ask questions and have had these answered.	
I understand that my participation is voluntary and I am free to withdraw at any time during the study without affecting my future healthcare.	
I give permission for study doctors, other health professionals, hospitals or laboratories outside this hospital to release information concerning my disease and treatment for the purposes of this project. I understand that such information will remain strictly confidential.	
I confirm I am happy for my personal data (name, NHS number and contact details) will be transferred to a country outside of the European Economic Area (EEA).	
I agree to my GP being informed of my participation in the study.	
I understand that I will be given a signed copy of this consent form to keep for my own records.	

Name of the participant _____

Signature_____

Date_____

Name of Investigator_____

Signature_____

Date_____

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Informed Consent Form

Additional Blood Samples

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Short Title REDDS2

Principal Investigator **INSERT LOCAL DETAILS HERE**

Site **INSERT LOCAL DETAILS HERE**

Declaration by participant

	Patients Initial and Date only
I confirm that I have read the information sheet date…..(Version…..) for the REDDS2 study. I have had the opportunity to consider the information, a ask questions and have these answered satisfactorily.	
I consent to providing an additional blood sample for bio banking	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my rights being affected.	
I understand the purposes, procedures and risks of the research described in the project from the Participant Information Sheet.	
I give permission for the study doctors, other health professionals, hospitals or laboratories outside this hospital to release information concerning my disease and treatment for the purposes of this project. I understand that such information will remain strictly confidential.	
I understand that I will be given a signed copy of this consent form to keep for my own records.	

Name of the participant _____

Signature_____

Date_____

Name of Investigator_____

Signature_____