|  |
| --- |
| Participant Information Sheet**Version 1.3 Date 30/08/2018** |

|  |
| --- |
| **ICaRAS trial****ICaRAS (IV Iron for Cancer Related Anaemia Symptoms) –** **A Feasibility Study of Intravenous Iron Therapy for Anaemia in Palliative Cancer Care.** |
| **Chief Investigator: Mr. Austin Acheson / Dr. Matthew Brookes****This study will form part of a doctoral thesis.** |

**PART 1**

**1. Invitation**

Thank you for considering your participation in this research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

PART 1 tells you the purpose of this study and what will happen to you if you take part.

PART 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

**2.** **What is the purpose of the study?**

To look at whether iron supplements given by injection to patients undergoing palliative care for cancer can be effective in treating anaemia and its related symptoms.

Doctors at the Department of Palliative Care are interested in helping people who are suffering from anaemia. Anaemia is a condition in which the patient suffers from a reduced level of hemoglobin, which is the substance in the blood stream that carries oxygen. Unfortunately, it is a common condition in patients diagnosed with cancer. There are different types of anaemia and it is important to identify the correct type because the treatments may be different. Patients suffering from anaemia may have a range of symptoms including shortness of breath, tiredness, lack of energy and chest pain, and so treating it may improve how patients feel and what activities they are able to do

**3.** **Why have I been chosen?**

You have been chosen because you have been diagnosed with cancer and are being supported with palliative care. Your doctor considers that you are appropriate for this trial and is happy for us to approach you. Recent blood tests have indicated that you are anaemic at the moment, i.e. that your blood count is lower than expected, and that you may benefit from treatment for this.

**4.** **Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will still keep records relating to the treatment given to you, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not in any way affect the quality of care you receive

**5.**  **What will happen to me if I take part?**

Upon deciding to enter the trial, you will be randomly assigned to one of two groups. The first group will be treated with a dose of intravenous (injected) iron for anaemia. The dose of intravenous iron is calculated based on body weight. In some patients, depending on their body weight, a second dose of intravenous iron will be given at a convenient time 7-10 days later. The second group will be offered a one-off dose of intravenous (injected) saline (salt water) as a placebo. Again, depending on body weight, some patients will be required to receive a second dose of intravenous saline 7-10 days after the initial dose. You will not be told which group you have been assigned to in order to avoid bias. Clinical research usually involves patients being split this way into two groups so that we can see the difference between patients who receive the new treatment and those who do not.

If you are taking any existing iron tablets you will be asked to stop these after agreeing with your consultant to ensure any results from the trial are accurate.

As compensation for extra hospital visits, we will offer you £20 to cover expenses.

In order to assess the effects of treatment both groups of patients will be required to give blood samples and stool samples at their initial visit and at visits at 4 weeks and 8 weeks to review any differences between the groups. Your blood will be tested to check the iron stores in your body and to check that your vital organs are working properly. The volume of blood taken will be 15ml (three teaspoons) collected at each visit.

**6.**  **What do I have to do?**

Everyone recruited to the study will be asked to complete quality of life questionnaires, known as the “FACIT-F fatigue score”, “EORTC QLQc30” and the “EQ-5D”. These are completed 3 times in total – at the start of the trial and then at 4 weeks and 8 weeks after administration of the injection.

We will give you a ‘FitBit’ pedometer (step-counter) to wear daily for a week prior to receiving the infusion and for a week prior to each of the two follow up visits. This will be used to assess your normal activity levels before and after the iron injection. You will also be asked to undertake a short activity assessment involving walking, sitting and standing at the initial visit and at the 4 and 8 week visits.

In order to assess the effect of iron on your gut bacteria we will ask you to provide a stool sample before the injection and at the 4 and 8 week visits after the injection. You will be given a sample collection pot to be used at home before each visit. Full instructions on how to collect the sample will be given by a member of the research team if you decide to participate in the trial.

The research team will collect information on you including medical history and medications, together with recording the blood results that you have as part of clinical treatment, but this will all be collected anonymously and recorded with a study identification number only.

Any additional treatments that are required will be decided by your doctor, but will be recorded by the research team.

You will be able to drive home after the study visits and continue with your normal daily activities.

A diagram has been included at the end of this sheet which should explain clearly what will happen if you agree to take part in the study. The overall length of time that you will be involved in the trial would be a maximum of 8 weeks. At most, four extra hospital visits will be required. However, where possible we will arrange for the study visits to coincide with any existing hospital appointments.

**7.**  **What is the drug / treatment that is being tested?**

The drug being tested is a fully licensed iron injection, called Monofer® (manufactured by Pharmacosmos®). The injection is also known by the scientific name, iron isomaltoside 1000. This medication has undergone rigorous safety testing and is considered safe for use. Similar drugs have been used to treat anaemia caused by other types of illness for many years.

**8.** **What are the alternatives for treatment?**

Anaemia that occurs at the same time as cancer can be treated by giving the patient extra iron. Iron can be given in the form of a tablet or more recently by injection or in some cases it is treated with a blood transfusion. Iron tablets are considered standard treatment but iron injections are a relatively new treatment. Blood transfusions are generally reserved for patients who are very symptomatic and require rapid treatment of the condition, or in those where other treatments have failed. This study will help us to correctly identify the type of anaemia and assess whether iron injections are an effective treatment method.

**9.** **What are the side effects of any treatment received when taking part?**

If you do decide to take part in the study, it is important that you report any problems you have to your study nurse or doctor. There is also a contact number given at the end of this information sheet for you to phone if you become worried at any time. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

Recognised side effects of Monofer® include headache, dizziness, nausea, abdominal pain, constipation, diarrhoea and rash. The majority of these side effects only tend to affect 1 in 100 patients.

A small minority of people may have an allergy to iron injections. Severe “anaphylactic” reactions are very rare and occur in less than 1 person per 10,000 given the drug. If you feel unwell after your treatment, let your study doctors know. You may require further medical treatment.

Some people may experience a local reaction to the iron injection. This is nothing to worry about and should settle down shortly after the injection is given.

**10.** **What are other possible disadvantages and risks of taking part?**

In some patients, the iron treatments may not be effective in treating the anaemia. These patients may require further treatment for anaemia.

For Women:

The treatment might harm the unborn child; therefore you should not take part in this study if you are pregnant, breast-feeding or you intend to become pregnant during the study.

If you are a woman who might become pregnant, you will be asked to have a pregnancy test

(urine or blood) before taking part. You must agree to use a reliable form of contraception during

the trial, e.g.

* Oral contraceptive + condom
* Intra-uterine device (IUD) + condom
* Diaphragm with spermicide + condom

This should be continued for at least 1 month after the treatment has finished.

**11. What are the possible benefits of taking part?**

We cannot promise this research study will help you but we hope that it will lead to improved care in the future for patients in a similar situation to yourself. The information you provide will help us to develop

future studies designed to give a definite answer as to whether intravenous iron is an effective way of treating anaemia for people in this situation. We are keen to find this out, as it may lead to a better quality of life by improving the symptoms of anaemia, such as tiredness, shortness of breath and dizziness.

This is the theoretical basis behind why we are performing this study.

**12. What happens when the research study stops?**

When the research study stops, your treatment will continue to be governed by the clinical team overseeing your care. Your clinical team will be consulted before you receive any treatment for the trial.

**13. What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. If you have concerns about the way you have been approached or treated during the course of the study, you may wish to contact the Patient Advice and Liaison Service (PALS) on:

 (insert local PALS details here)

|  |  |
| --- | --- |
|  |  |

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone’s negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**14. Will my taking part in this study be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential. Details are included in Part 2.

**15.** **Contact Details:**

**Doctors:**

Name:

 Mr Austin Acheson

 (Associate Professor GI Surgery) Austin.acheson@nottingham.ac.uk

Division of GI Surgery 01159249924

 E Floor West Block

 Queen’s Medical Centre, Derby Road,

Nottingham, NG7 2UH

Dr Matthew Brookes matthew.brookes@nhs.net

Consultant Gastroenterologist 01902 307999

Department of Gastroenterology

Royal Wolverhampton NHS Trust

**New Cross Hospital,**

**Wolverhampton Road,**

**Wolverhampton,**

**WV10 0QP.**

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

**PART 2**

**16. What if new information becomes available?**

Sometimes during the course of a clinical trial, new information becomes available on the drugs that are being studied. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue.

**If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.**

**17.** **What will happen if I don’t want to carry on with the study?**

You can withdraw from treatment at any point that you wish but keep in contact with us to let us know your progress. Information collected may still be used. Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish. Your medical care will not be influenced in any way.

If you loose mental capacity (the ability to make your own decisions or choices) during the study, for example through illness or disability, you will be withdrawn from the study. Any information or data collected until this point will still be used unless you specifically object.

**18. Will my part in this study be kept confidential?**

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital and the Queen’s Medical Centre under the provisions of the 2018 General Data Protection Regulation (GDPR). Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor for example your GP or clinical team if any abnormalities are detected in your blood tests that need further treatment. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

***The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.***

If you withdraw consent from further study treatment, unless you object, your data and samples will remain on file and will be included in the final study analysis.

In line with GDPR, at the end of the study, your data will be securely archived for a minimum of 25 years. Arrangements for confidential destruction will then be made. With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study,and as mentioned above, may be contacted if the research team identify any abnormalities requiring further treatment.

**19. Use of your Personal Data in Research**

Nottingham University Hospitals NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Nottingham University Hospitals NHS Trust will keep identifiable information about you for 25 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, unless you specifically object we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information [www.nuh.nhs.uk].

*(Insert site name)* will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from *(Insert site name)* and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in *(Insert site name)* who will have access to information that identifies you will be people who need to contact you or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

**20. Informing your General Practitioner (GP**

On entering the trial, we will ask your permission to inform your GP. This is so that they are aware of any changes to your medication.

**21. What will happen to any samples I give?**

All samples will be handled in the routine manner by the Pathology laboratories within the Trust. This may involve being sent to another NHS laboratory. Following the end of the trial any remaining samples will be stored in the (insert local biobank name) and may be used in future research. Storage of samples will be in a locked facility only accessible by authorized members of the research team. They will only be identifiable by your unique trial number.

**22. Will any Genetic testing be done?**

No. There will be no genetic testing performed.

**23.** **What will happen to the results of this clinical trial?**

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication. Should you wish to see the results, or the publication, please ask your study doctor.

**24.** **Who is organising and funding this clinical trial?**

The Nottingham University Hospitals NHS Trust will act a sponsor the research. The National Institute for Health Research will fund the research.

**25**. **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the Nottingham (East Midlands) Research Ethics Committee. The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust.

**26. Contact for further information**

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the drug(s)/procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in

your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor. You can have more time to think this over if you are at all unsure.

**Thank you for taking the time to read this information sheet and to consider this study.**

**The Patient Pathway:**

|  |
| --- |
| **Screening.**Patients with cancer and anaemia suitable for treatment with palliative intent  |
|  |
| **First appointment.** Trial explained |
|  |
| **Patient accepts** |  | **Patient declines** ***Continue standard clinical care*** |
|  |
| **Recruitment.** Full screening and Consent |
|  |
| **Randomisation** |
|  |
| **Baseline Clinical Assessment.**Blood tests, questionnaires, pedometer given, SBBP assessment, faecal sample |
|  |
| **Group 1.** Placebo**IV saline administered** |  | **Group 2.** Iron infusion**IV iron administered** |
|  |
|  |
| **IV saline administered** ***if required at 7-10 days*** |  | **IV iron administered*****if required at 7-10 days*** |
|  |
| **Attendance for 4 week follow up.**Outcomes assessment, blood tests, faecal samples, questionnaires and pedometer reading |
|  |
| **Attendance for 8 week follow up.** Outcomes assessment, blood tests, faecal samples, questionnaires and pedometer reading |
|  |
| **Trial completion.** |