

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*Frankston Hospital*

|  |  |
| --- | --- |
| **Title** | *Ultrarapid iron polymaltose infusion for iron deficiency anaemia: a pilot safety study* |
| **Short Title** | *UltraRIIPH pilot study* |
| **Protocol Number** | *2* |
| **Coordinating Principal Investigator/ Principal Investigator** | *Iouri Banakh* |
| **Associate Investigator(s)** | *Martha Turek, Dr Jong Chin, Dr Travis Churchill* |
| **Location** | *Frankston Hospital* |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you have been diagnosed with iron deficiency anaemia and have been prescribed an iron infusion as part of your treatment.This research project is testing the safety of giving an iron infusion at faster rates than previously used.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Iron deficiency and anaemia are common conditions. They are treated by increasing your body’s iron levels . The most common way is by mouth as an iron tablet or liquid. Some people may need iron to be given directly into the blood through a vein, and this is called an intravenous (IV) iron infusion. An IV iron infusion is used when tablets or liquids do not work for a person or when they cause side effects such as stomach upset.

In the past, iron polymaltose (a type of IV iron) was only given as an IV infusion over 4 hours. These days, it can be given faster and safely over 1 hour (for doses up to 1500 mg) thanks to the results of recent studies. Another type of IV iron, ferric carboxymaltose, is frequently used and can be given over just 15 minutes. However, it is more expensive and can only deliver a maximum dose of 1000 mg per week. Most people need around 1500 mg to completely top-up their iron and to last them for months or even up to a year. Previous studies suggest that how quickly IV iron is given has no effect on how well this treatment is tolerated. For this reason, the goal of this study is to test the safety of iron polymaltose given over 30, and then potentially over 15 minutes. Safety results will be compared to the slower infusions and to the other type of IV iron, ferric carboxymaltose. If no difference in safety is found, then this could be a better option because patients can be treated with a complete iron top-up and have it done over a shorter period of time. Infusion centres and hospitals would also benefit with reduced nursing time, larger number of patients treated and reduced direct medication costs.

Iron polymaltosehas been approved in Australia to treat iron deficiency anaemia since 27 May 1999. However, it is not approved for infusion rates over 15 or 30 minutes. Therefore, it is an experimental method of giving this treatment for iron deficiency anaemia. This means that it must be tested to see if it is as safe as the usual way of giving it over 1 or 4 hours.

This research has been initiated by the study pharmacist, Mr Iouri Banakh and medical staff from Gastroenterology and General Medicine.

**3 What does participation in this research involve?**

If you are diagnosed with iron deficiency anaemia and are a patient at Frankston Hospital needing an iron polymaltose infusion of up to 1500 mg, you could participate in this study. The investigators of this study will have sought approval from your treating team prior to approaching you for potential enrolment as a participant. You must be able to read English and provide informed written consent before receiving the iron infusion order at the study infusion rates of over 30 minutes (group 1) or 15 minutes (group 2).

The required dose of iron polymaltose will be calculated by medical and pharmacy staff using established guidelines. The infusion will be prepared by the Pharmacy Department as per standard procedure. It will be given directly into the blood through a vein by nursing staff. As a participant, you would be monitored by a doctor of the research team for the duration of the infusion. Nursing staff will continue to monitor you for one hour after the infusion and doctors will be called in case of any side effects, as per current iron infusion guidelines. Monitoring will include pulse, blood pressure, temperature, and oxygen levels every 5 minutes. Any reported side effects will be recorded. If you experience side effects, you will be able to complete the infusion at a slower rate or, if the reactions are severe, you will have your infusion stopped and restarted only after medical review and if considered safe. The treatments of side effects are the same as when the infusion given slower, over 1 or 4 hours. After monitoring for 1 hour, no further involvement is required and you may go home or complete your other hospital treatments. One week after your iron infusion you will receive a phone call from one of the study investigators to check if you have experienced any side effects, and in the event that you have, the severity and treatment of side effects will be recorded.

Investigators will collect information from your history and/or digitised medical records and the electronic medication management system. All collected information will be recorded on confidential collection forms that do not identify you by name nor hospital number. Information collected will include:

* your age, gender and weight
* the cause of your iron deficiency (if known)
* blood test results before your infusion
* if you had any recent blood transfusions in the last 2 weeks
* your other medical conditions and medications you were taking at home before coming to hospital
* if you received any medications used to prevent side effects
* your iron polymaltose dose and infusion rate
* your risk factors for side effects
* any side effects recorded in the history notes or observed during the monitoring period
* if you received any treatments for side effects
* if you had any adjustments made to your infusion rate
* if you needed the infusion to be stopped and/or restarted

For the purpose of collecting information on side effects 1 week after the infusion, your name and preferred phone number will be kept until the phone call has been made and the information collected. After this your personal identifiable information be will not be kept.

Should you provide informed written consent, you will be participating in an open-label study. This means that no attempt is made to disguise the treatment. Therefore, both you and the study investigators are aware of what type of treatment you are receiving. The expected duration of this study is 3-4 months based on current rates of iron infusions prepared by the Pharmacy Department. Participant involvement only lasts for the duration of the infusion and the monitoring period of 1 hour straight after the infusion.

This is a pilot study, meaning a small-scale study carried out before that of a larger planned project. It is helpful in the process of designing and setting up a larger-scale research project.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study investigators or participants misinterpreting the results.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

Your general doctor (GP) will be informed that you have received an iron infusion during your hospital admission through a discharge summary provided by the hospital doctors. If you experience any side effects within a week of going home you should let your GP know and if you wish you can contact the hospital study investigation team. The contact details for the study investigation team are included in this consent form.

**4 What do I have to do?**

This study does not require you to apply any restrictions on your lifestyle or diet. Your regular medication can continue as usual. However, if you were taking an iron supplement in the form of oral tablets or liquid, this would need to stop when receiving treatment with iron polymaltose. Oral iron supplements should not be restarted for a week after having your infusion because the iron in them will not be absorbed by the body. They are also often not needed after an iron polymaltose infusion. Check with your local doctor if and when oral iron supplements are needed.

After the infusion is complete, it is recommended to stay at the hospital for one hour for monitoring for side effects, regardless of your decision to participate in this study. Unless you have an unexpected reaction, you will be able to drive home and do your normal activities. If you have any side effects after the iron infusion is complete, please let your nurse know if you are still a patient at the hospital, otherwise let one of the study investigators know when they call 1 week after the infusion. In case of any distressing side effects, please contact your local doctor and In case of any emergency call 000 for an ambulance.

**5 Other relevant information about the research project**

This study will enrol 20 participants in total at Frankston Hospital. The first ten participants (group 1) will receive 30-minute infusions. Another ten participants (group 2) will receive 15-minute infusions if no safety issues arise with group 1.

Iron polymaltose infusions were normally given over 5 hours. They used to also require a ‘test dose’ for the first 15 minutes where the infusion was even slower. Recent research by some of the investigators of this study has shown no difference in safety risk with faster infusion rates over 1 hour for doses up to 1500 mg. It was also found that test doses are of no use and are no longer recommended by the European Medicines Agency. These findings have been incorporated into the hospital guideline and, as such, have become standard practice.

This study aims to explore the safety of giving iron polymaltose at even faster rates – further testing the theory that faster rates are no different in safety compared to the slower infusions.

The researchers of this study are all employed at Frankston Hospital as pharmacists and doctors.

**6 Do I have to take part in this research project?**

Participation 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 project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Peninsula Health.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Another option is available, which is to have your iron infusion given as per our hospital’s current guideline over 1 hour rather than over 15 or 30 minutes. The risks of side effects with having the infusion over 1 hour are known are the same as having the infusion over 4 to 5 hours. Even though that risk is low, it is not known whether the risk and severity with a faster infusion will be the same, better or worse. Your study doctor or pharmacist will discuss this option with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include a shorter period of stay at the hospital and having your total iron replacement completed in one session rather than needing to come back in 1 week to have another treatment. This could also significantly benefit infusion centres and hospitals with reduced nursing time and direct medication costs.

**9 What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them:

* during your infusion, tell your study doctor who will be monitoring you,
* in the hour after your infusion or if you remain in hospital after it is completed, tell your nurse who can alert a doctor if required,
* after the infusion and when you have been discharged, talk with your local doctor. **If you have chest pain, trouble breathing, dizziness or neck / mouth swelling, please seek urgent medical attention / call an ambulance (000).**
* 1 week after the infusion you will receive a phone call from the study investigator, please inform them of any side effects that you may experience, their severity and treatment.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Less than 1 in 10 patients experience any side effects during usual iron polymaltose infusions. For those who do, the reactions are mild to moderate in severity and last for short periods of time. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. The infusion may be restarted only after medical review and if considered safe. Your study doctor will discuss the best way of managing any side effects with you.

The most common side effects are temporary and include:

* headache, fever, feeling flushed or sweaty
* feeling sick or vomiting, dizziness
* rash or itchiness
* muscle or joint pain
* changes in taste (e.g. metallic)
* changes to blood pressure or pulse

Having an iron infusion involves having a needle placed into a vein in an arm for the duration of the infusion. This may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

Skin staining (brown discolouration) may occur due to leakage of iron into the tissues around the needle site. This is not common, but the stain can be long lasting or permanent.

Although very uncommon, some people may have a serious allergic reaction. In rare cases this can be life-threatening.

Some patients may experience delayed side effects up to a week after the infusion, commonly headache, muscle or joint pain. Mostly they will settle down by themselves over the next few days.

Anaemia symptoms and signs (fatigue, weakness, and reduced mental alertness) take several weeks to a month to improve.

If treatment of a side effect is required with medication after discharge, you will be charged for that medication as you are for any medications you receive on discharge from the hospital. This is regardless of whether you choose to participate in this study.

**10 What will happen to my test samples?**

As part of the procedure for receiving an iron infusion, you would have had prior blood tests to determine you have iron deficiency and to help calculate your required dose for iron replacement. No further collection of any samples will occur once you are enrolled into the study. Data collection and analysis will include review of your blood tests results in a de-identified manner.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular healthcare to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

**12 Can I have other treatments during this research project?**

Regardless of whether you choose to participate in this study, you should not take any oral iron supplements for a week after having your iron infusion because the iron in them will not be absorbed by the body. They are also often not needed after an iron polymaltose infusion. Check with your local doctor if and when oral iron supplements are needed.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

All other treatments that you are prescribed can continue and you will be advised on this by the hospital doctors and pharmacists before your discharge.

**13 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify your nurse or a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing. As well as facilitate an alternative treatment option for your iron replacement.

If you withdraw your consent during the research project, the study investigators will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**14 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. The most likely would be due to unacceptable side effects in terms of severity.

**15 What happens when the research project ends?**

The results will be submitted to the Human Research Ethic Committee and Drugs and Therapeutics Committee, and if considered significant submitted to a medical or pharmaceutical journal for publication.

Given the pilot-nature of the study only enrolling 20 participants, any evaluation of results cannot be determined with confidence. Therefore, the results are for more exploratory purposes and cannot be expected to change practice or guidelines. We would require a larger group of participants (almost 300) to be able to make more accurate conclusions. Plans to expand the research project will be pursued with the help of this study’s design.

Iron polymaltose infusions will continue to be available over 1 hour for doses up to 1500 mg and over 4 hours for larger doses.

If you choose to participate in the study you will know your own personal results. If you would like to know the results of the entire study, then let a member of the investigation team know so that we can obtain your preferred method of providing the results to you. The results are anticipated to be available within 6 months of your participation.

**Part 2 How is the research project being conducted?**

**16 What will happen to information about me?**

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

All information will be coded at the time of data entry on data collection forms. It will be de-identified after all the information is collected. Information about your participation in this research project may be recorded in your digitised medical records. By signing the consent form you agree to the study team accessing these records if they are relevant to your participation in this research project.

Hard copies of data collections forms, consent forms and withdrawal of participation forms will be stored at the Frankston Hospital Pharmacy Department for 7 years, accessible only by the investigating team. These records will then be destroyed by placement into a Peninsula Health confidential bin by an investigator. An electronic copy of the results will be kept on the Peninsula Health Pharmacy network drive in a de-identified format.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**17 Complaints and compensation**

Complaints by participants about the conduct of this research project may be directed to the people named in Section 20:

* The study team member named at the end of this document
* The Convenor

Human Research Ethics Committee

C/- Manager Office for Research

Peninsula Health

PO Box 52

Frankston Vic 3199

Tel: (03) 9784 2679

Email: ResearchEthics@phcn.vic.gov.au

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the event of any side effects, the hospital and the study team will not provide any compensation beyond treatment of the side effect(s).

**18 Who is organising and funding the research?**

This research project is being conducted by Mr Iouri Banakh (Clinical Pharmacist) in conjunction with the Gastroenterology and General Medicine units of Frankston Hospital.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Peninsula Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study investigator, Iouri Banakh, on 0413 092 113 or any of the following people:

* Martha Turek on 0431 543 805
* Dr Jong Chin on 0425 019 999
* Dr Travis Churchill on 0435 916 758

**Clinical contact person**

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| --- | --- |
| Name | Iouri Banakh |
| Position | Pharmacist, Principal investigator |
| Telephone | 0413 092 113 |
| Email | ibanakh@phcn.vic.gov.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

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| --- | --- |
| Position | Manager office for Research |
| Telephone | (03) 9784 2679 |
| Email | researchethics@phcn.vic.gov.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | Peninsula Health Human Research Ethics Committee |
| HREC Executive Officer | Manager Office for Research |
| Telephone | (03) 9784 2679 |
| Email | researchethics@phcn.vic.gov.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | *Ultrarapid iron polymaltose infusion for iron deficiency anaemia: a pilot safety study* |
| **Short Title** | *UltraRIIPH pilot study* |
| **Protocol Number** | *2* |
| **Coordinating Principal Investigator/ Principal Investigator** | *Iouri Banakh* |
| **Associate Investigator(s)** | *Martha Turek, Dr Jong Chin, Dr Travis Churchill* |
| **Location** | *Frankston Hospital* |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Peninsula Health concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation -** *Adult providing own consent*

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| --- | --- |
| **Title** | *Ultrarapid iron polymaltose infusion for iron deficiency anaemia: a pilot safety study* |
| **Short Title** | *UltraRIIPH pilot study* |
| **Protocol Number** | *2* |
| **Coordinating Principal Investigator/ Principal Investigator** | *Iouri Banakh* |
| **Associate Investigator(s)** | *Martha Turek, Dr Jong Chin, Dr Travis Churchill* |
| **Location** | *Frankston Hospital* |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Peninsula Health.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

**Reason for withdrawal**

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.