PARTICIPANT INFORMATION SHEET
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Study Title: IRON WOMAN – Iron therapy for female athletes

Chief Investigator: Professor Toby Richards
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Principal Investigators: Dr Charles Pedlar and Dr Richard Burden

You are being invited to take part in this pilot research study as a result of your recent expression of interest in our work. Before you decide whether to participate, 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. Please do us if there is anything that is not clear or if you would like more information.

Study Purpose and Research Overview
This study is being conducted to fulfil the requirements of a Graduate Research Degree (PhD) being undertaken by Miss Georgie Bruinvels, Division of Surgery and Interventional Science at University College London (UCL).

Our research group aims to optimise the health and well being of athletes. The research group at St Mary's University, Twickenham in collaboration with UCL is specifically looking at the effects of low iron (i.e. iron deficiency anaemia and iron deficiency non-anaemia) and it's impact on performance.
Endurance exercise can cause small iron loss through haematuria (blood in urine), gastrointestinal bleeding, sweating and haemolysis (destruction of red blood cells, particularly exacerbated in impact sports involving foot strike). Females who participate regularly in endurance training therefore have an increased susceptibility to iron deficiency, and this is likely to be exacerbated in menstruating females. Iron is essential for the healthy functioning of the body and deficiency will eventually result in a reduction in energy levels, weakness, impaired cognition and motivation amongst other long-term detrimental affects to the human body.

The purpose of this study is therefore to see whether intravenous iron supplementation improves exercise performance and quality of life in iron deficient exercising women.

Why have I been invited to take part in this study?
We are contacting you because you have indicated that you may be low in iron and exercise on a regular basis.

Do I have to take part in this study?
You are under no obligation to take part in this research, participation is voluntary, but if you do decide to partake please read and keep this information sheet, and sign the consent form at the end. If you decide that you no longer want to be a part of this research then you will be able to withdraw safely, at any time with no notice or reasoning. Declining to take part or withdrawing from this study will have no impact on future care or involvement in other research.

What will happen to me if I take part in this study?
You are being contacted because you think you may meet our predefined criteria for being iron deficient. If you decide that you would like to continue involvement in this study you will undergo some tests and answer some questionnaires, then be given a single injection of iron. The initial tests and completion of questionnaires will then be repeated on one or two occasions. The aim of giving you iron is to return your iron levels to a 'clinically normal' level. You will need to visit St Mary's University,

Twickenham on four occasions for a number of tests, and 112 Harley Street, London as explained below;

1. Screening test – this will involve having a blood test to check your iron status to see if you are eligible for this research. During the visit to the lab you will be given an overview of the study and will be able to ask questions. This will take place at St Mary's University, Twickenham.

2. Baseline testing – you will be required to have an exercise test (the test is called a VO_{2max} test, and it measures the maximum amount of oxygen that you can take in and use while exercising. It is the main test used in exercise physiology to assess physical fitness, and a higher value indicates a higher level of fitness), a blood test, a total haemoglobin mass test (explained below), provide a urine sample and answer 5 questionnaires (approx. 2 hours for all tests). This will take place at St Mary's University, Twickenham.

3. Iron injection - after the baseline tests you will be required to go to the iron therapy clinic located at 112 Harley Street, London to receive an iron injection. This will be given by a trained medical professional. Iron will be infused over a minimum period of 15 minutes and you will be observed for 30 minutes after this. (approx. an hour in total)

4. Follow up testing – 2 weeks after you have had the iron injection you will be required to come back to St Mary's University, Twickenham and repeat the tests that were performed at baseline, including – an exercise test, a blood test, a total haemoglobin mass test, provision of a urine sample and to complete the 5 questionnaires. 3 months (12 weeks) after the iron injection you will be required to come back to St Mary's again for a blood test and to answer the 5 questionnaires.

How long am I likely to be in this study?
After you have come into the lab for your familiarisation trial you will complete your baseline tests, you will receive your iron injection within the next 2 weeks, follow up testing will take place 2 weeks and 3 months (12 weeks) after this. Therefore from the baseline testing you will be in the study for approximately 16 weeks.

What are the possible benefits of taking part in this study?
You will receive information about your current level of physical fitness, and will be given key target training and heart rate zones that you can use for your training. You will also gain information about your general health and well-being. If your iron deficiency is having an impact on your quality of life and exercise performance you will also benefit from the restoration of your iron levels.

What are the possible side effects, disadvantages and risks of taking part in this study?
The risks associated with a VO_{2max} test are minimal but include the following: fatigue, muscle soreness, irregular heartbeat and chest pain. We will conduct testing in the standardised procedure under the guidance of an experienced exercise physiologist; heart rate and rate of perceived exhaustion will be continuously monitored throughout the test in a controlled environment.

We will also require you to complete a total haemoglobin mass test. This test is routinely used in sport and exercise science and provides another way of measuring fitness, showing how much oxygen your body can transfer. The test involves breathing a very small amount of carbon monoxide, less than you would breathe in when sitting in a queue of traffic. This will be performed by a trained physiologist, and is very unlikely to have any effects on your health and wellbeing.

The most common reported side effects of intravenous iron are dizziness, high blood pressure and/or injection site reactions.

Other uncommon side effects (occur in less than 1 in 100 (1%) and more than 1 in 1,000 (0.1%) patients receiving iron) are allergic reaction (hypersensitivity), sensation of pain (paraesthesia), a change in your taste sensation (dysgeusia), high heart rate (tachycardia), low blood pressure (hypotension), redness in the face (flushing), difficulty breathing (dyspnoea), vomiting, upset stomach (dyspepsia), flatulence, abdominal pain, constipation, diarrhoea, itching (pruritus), hives (urticaria), redness of the skin (erythema), rash, muscle, joint and/or back pain (myalgia and arthralgia), muscle spasm, fever (pyrexia), tiredness (fatigue), chest pain, swelling of the hands and/or the feet (oedema peripheral), pain and/or chills.

In all the clinical trials reported to date (including over 6000 patients) there has been no report of increased side effects in patients receiving the intravenous iron compared to those patients who received the placebo.

If you encounter any problems following the IV iron treatment you should contact Professor Toby Richards immediately (Tel: 0207 679 6454).

Is it compulsory for me to take part?
No, it is not compulsory; participation is voluntary and specific to this study. If you do agree to be involved in this study it does not mean that you agree to being involved in other studies.

What are the alternatives for treatment of iron deficiency?
In the UK, typically iron is given in tablet form, however this is typically poorly absorbed and there are some side effects including abdominal pain, constipation and heartburn. Also, restoration of iron stores typically takes 3-6 months. Additionally, those who exercise may have increased levels of inflammation, which will hinder absorption. Conversely, intravenous iron which can be administered as a single treatment in a relatively short length of time (minimum of 15 minuets) enables rapid restoration of iron status. Intravenous iron is widely and effectively used in countries such as Switzerland and Australia.

Why will iron be delivered intravenously and not orally?
As restoration of iron stores is slow and poorly absorbed through oral iron treatment intravenous iron therapy is being used. This has been shown to be much more effective.

What will happen if I do not want to carry on with the study?
If you decide during the study that you no longer want to participate you can withdraw yourself at any time and do not need to give a reason. After study completion, any stored blood or tissue samples that can still be identified as yours will be destroyed if you would like.

If there is anything you do not understand or wish to ask questions about, please feel free to ask.

In the unlikely event of a loss of capacity to consent, the research team will retain tissue and personal data collected during this study and continue to use it confidentially for research purposes. This could include further research after the current project has ended.

What if something goes wrong?
In the unlikely event that you are harmed while taking part in this research project, there are no special compensation arrangements. But, if you are harmed due to someone's carelessness, then you may have grounds for legal action but you may have to pay for it.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. You will be referred to by a unique code, and any information about you will have your name and address removed so that you cannot be recognised.

Will my General Practitioner be notified?
On agreement, your general practitioner will be informed of your inclusion and will be provided with your results from this research.

What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the subject being studied. Should this happen a member of the research team will tell you about it and discuss with you whether you want to continue in the study.

What will happen to the results of the research study?
Results will be published in a peer-reviewed scientific journal once the study is completed. You will be given with a lay summary of the research results. You will not be identified in any publication.

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 interests. This study has been reviewed and given favourable opinion by the London-Westminster Research Ethics Committee.
The St Mary's University Ethics Committee has also reviewed and approved this research.

What will happen to any samples I give?
Any blood samples that are taken as part of the research study will be transferred to a central laboratory for analysis. The blood will only be identified by using your unique study number. The blood will be frozen at -80°C. The samples will be transported to a laboratory in central London called The Doctors Laboratory (TDL). The bloods will be analysed. Any serum excess (blood product) will be stored for future research. All results will be sent to the statistician who is based at the London School of Hygiene and Tropical Medicine (LSHTM). This is where the staff organising this study are based.
Unless you withdraw your consent, we will ask you to gift your blood to the people running the study and in so doing give up all future claims to its use that may include further research.

If you wish to find out more about this research study, you can contact:

Georgie Bruinvels – georgie.bruinvels@stmarys.ac.uk; georgie.bruinvels.14@ucl.ac.uk

Thank you for taking time to read this information.