Participant Information leaflet

Treatment of Iron deficiency Anaemia in Pregnancy - (TIAP) study

Full Title of Study: Iron deficiency anaemia in pregnancy: an observational study of tolerability, compliance with oral iron therapy and effects on haematological/biochemical markers

Chief Investigator: Mr David Churchill

Invitation to take part in a research study

We would like to invite you to take part in the TIAP study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information leaflet with you, to help you decide whether or not you would like to take part and answer any questions you may have. This should take about 20 minutes. Please take time to read the following information carefully and discuss it with others if you wish. Ask your doctor or nurse if there is anything that you do not understand or if you would like more information. Take time to decide whether or not you wish to take part in this research study

What is the purpose of the study?

Iron deficiency anaemia is a common condition in pregnancy. It affects between 30% to 40% of pregnant women. Anaemia can make pregnant women feel tired and unwell. There is some evidence that anaemia may also increases the risk of babies being born prematurely and/or underweight. The evidence shows that anaemia could also be a risk factor for stillbirth and neonatal death. It can also be a real problem around the time of delivery if a mother bleeds when she is already anaemic. This increases the chance of her anaemia carrying on after pregnancy leading to more risk of infections and problems with breast feeding. Also, in more severe cases there will be more need for a blood transfusion.

Although we know how to treat this type of anaemia we don't know how effective the treatment is, or how severe the side effects are for pregnant women. In fact, we know that many pregnant women are troubled by these side effects and thus don't take the iron in the recommended way.

This study aims to:

1. find out how tolerable the recommended iron treatment is for pregnant women and for women in the postnatal period.
2. investigate the effects of iron therapy:
    - on the level of haemoglobin; this is the protein that carries oxygen in the bloodstream,
    - its effect on the symptoms of anaemia, and

- the side effects that are caused by the treatment.

3. look at some new proteins in the blood that regulate the uptake of iron to see if we can better understand the body response to iron therapy.

Why have I been invited to take part?

You are being invited to take part because your haemoglobin level is lower than expected making you anaemic. It is routinely recommended that you receive treatment for the anaemia, and thus will be prescribed iron therapy. This makes you a potential candidate to take part in this study. We therefore invite you to take part.

Do I have to take part in the study?

No. The decision on whether you take part in the study or not is entirely yours. *If you do decide to take part, you are still free to withdraw at any time and without giving a reason. If you choose not to participate, this will not affect the care you or your baby get from your own doctors.*

What will happen if I do take part?

Most of your care will be based on the current routine national care recommended by the British Haematology Society for the treatment of anaemia in pregnancy or the postnatal period if you have delivered. As such, it will be not much different from the care that should be given to any other anaemic woman in pregnancy. To this end, you will be prescribed oral iron, instructed on how best to take it, and followed up a few weeks later to see if the treatment is working. If it is, you will then continue with the treatment for 3 months or until delivery (whichever is earlier) as per normal practice. If it is not working, we will then offer you either an alternative way of taking the iron tablets or an intravenous iron therapy (see Appendix 1 below). Again, this is in line with normal best practice. We will also want to monitor the growth of your baby which is also routine practice.

What will be different is that instead of being seen through the normal routine antenatal clinic you will be invited to the 'anaemia research clinic' for the follow up visits. You will be seen by an obstetrician who is also a research doctor. The rest of your antenatal care will be as normal.

Another requirement of this study is to complete quality of life questionnaires, anaemia in pregnancy assessment questionnaire, and a diary about the symptoms you may experience during the 2 – 4 weeks from starting the iron treatment until your next follow up appointment(s) (see Appendix 1). The questionnaires aim to find out about your mood and feelings during pregnancy as well as any factors that helped or blocked you from taking the iron treatment. The diary includes questions about the symptoms of anaemia and the side effects from iron that you might be suffering during the treatment period. The number of times you will be asked to complete these questionnaires and diary varies (between 2-4 times for the questionnaires, and 14-42 days for the diary) depending on how you respond to the iron treatment as detailed in flowchart below (Appendix 1).

Finally, when we take the routine blood samples to see if the treatment is working, we will take an extra blood samples at each visit specifically for this study (an extra 10 mls or 2 teaspoons of blood, will be taken at each visit (for further details see Appendix 1 below). This means a total of 30 mls will be taken for those who respond to iron straight away. For those small number of women who do not respond and need to have their iron dosage

adjusted an extra 10 mls of blood will be taken at the subsequent follow up visit, making 40 mls in total for these women. For women recruited after delivery a total of extra 20mls will be taken). The extra, research samples of blood will be assigned a unique study number and your initials, and no identifying information will be used on labelling to ensure that your anonymity is protected. We will then send these extra samples to two laboratories, one in Wolverhampton University and one in Oxford, for further analysis of specific proteins, such as hepcidin, cytokines and markers of iron metabolism. This analysis may, in the future, help us to develop a test that is better at assessing the success of treatment and help us to refine the iron therapy. Once the analysis on you blood samples is performed, your blood samples will be immediately destroyed.

What are the possible risks of taking part?

There is no risk to you or to your baby in taking part in this study as we are following routine standard care and treatment of anaemia. There may be some inconvenience in completing the study diary and questionnaires.

What if I suffer side effects from the iron treatment?

Part of the aim of the study is to discover what side effects women suffer from and how troublesome they prove to be to women. If you suffer side effects please note them in the diary we provide and inform the research doctor at your next visit. If you should have a severe reaction, then please contact us using the contact numbers at the end of this leaflet and we will give you further advice on what to do.

Will taking part in the study be kept confidential?

Yes, all the information that is collected about you during the study will be kept strictly confidential and secure in line with the law as set out in the General Data Protection Regulation.

The Royal Wolverhampton NHS Trust is the sponsor for this study based in England. We will be using information from you and 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. the Royal Wolverhampton NHS Trust will keep identifiable information about you for a minimum of 5 years after the study has finished.

The Royal Wolverhampton NHS Trust will use will keep 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.

Your data collected for the purposes of the study will be coded with a unique study number and your initials. The data will be held by the study team in The Royal Wolverhampton NHS Trust and stored in a secure research database separate from the hospital clinical record. The only people in The Royal Wolverhampton NHS Trust who will have access to information that identifies you will be people (from your care team) who need to contact to collect information for the study purposes or audit the data collection process. The only individuals with access to this database and documents linking your unique study number with your clinical record will be the Chief Investigator, Mr Churchill and his research team at the Royal Wolverhampton NHS Trust. We will keep details of your name and hospital number so that we can contact you for purposes of the study. No other information

collected for the study will identify you or your baby. Data containing your personal information will be kept in your local hospital as per local policy and for at least 5 years after the study had ended. Anonymised data about you will also be kept in this secure location for a minimum of 5 years. After this time, it will be destroyed.

During the study in addition to the data we collect from the symptoms and side effect diary we will need to access relevant sections of your medical notes. We will collect information on your baby at the time of birth. This information will be obtained from your records. We will not require, nor obtain any information from the child medical record. This information will be coded with unique study number and initials (as discussed above) so that you cannot be identified. Anonymised data will be shared with Oxford to enable the analysis to be carried out.

Certain individuals from the study sponsor and the regulatory authorities may look at your medical and research records to check the accuracy of the research study and to ensure that we are complying with the guidelines. 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.

What if relevant new information becomes available?

Sometimes we receive new information about the treatment we are studying. If that happens and it is likely to affect your participation in our study this will be discussed with you. Then you will be free to decide whether to continue or withdraw from the study. If you withdraw your care will not be affected in any way.

What will happen if I don't want to carry on with the study?

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, we will keep the information about you that we have already obtained. You can withdraw from the study at any point without giving a reason. If you decide that you no longer wish to take part, then simply inform either the research obstetrician or midwife. You can phone write or email or simply tell us at one of your appointments. If in the unlikely event that you lose your capacity to give consent (the ability to make informed decisions) once the study has started (between visits), then the data collected up to that point will be used for the study but no further information will be collected. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at:
http://www.royalwolverhampton.nhs.uk/patients-and-visitors/privacy-ico/

What if there is a problem?

If at any stage, you have concerns about the study or the way it has been carried out you should tell either the research obstetrician or midwife who are conducting the study or Mr Churchill, the Chief Investigator. You can also talk to the Patient Advice and Liaison Service (PALS) in the hospital (contact details are below).

If you remain unhappy and wish to complain formally you can do this through the NHS complaints procedure. Ask any one in the clinic and you will be provided with an appropriate information leaflet.

Taking part in the study does not alter your legal rights in any way if you have grounds for legal action.

Will my General Practitioner be involved?

With your consent, we will inform your GP that you are taking part in the study.

What will happen to the results of the research study?

At the end of the study we will analysed results and publish in medical journals. However, neither you nor your baby will be identified in the publications. We may also use the results to apply for other research projects depending upon what we find from this study. If you want a copy we can send one to you.

Who is organising the research?

The research is being organised by The Royal Wolverhampton NHS Trust, the NHS Blood and Transplant Service (NHSBT) and the National Perinatal Epidemiology Unit (NPEU) University of Oxford.

Who has reviewed the study?

The study has been reviewed by the Health Research Authority NHS Research Ethics committee (West Midlands - Black Country Research Ethics Committee- REC Reference: 18/WM/0090) and the Research & Development Department of the Royal Wolverhampton NHS Trust Peer Review Group.
Dr Hind Ali and Dr M Moussa are the Research Obstetricians carrying out the work assisted by the Research Midwives K Cheshire and J Icke. Mr D Churchill, Consultant Obstetrician, is supervising the project.

What happens now?

If you are interested in participating with the study, we will guide you through the consent process and start with the initial assessment.

Who should I contact for further information?

If at any time during the study you have questions or concerns regarding the study you can contact the Research Team:

- Mr D Churchill, Consultant Obstetrician, The Royal Wolverhampton NHS Trust, New Cross Hospital, Wednesfield, Wolverhampton, WV10 0QP. Tel: 01902 695153
- Dr H Ali, Research Fellow, The Royal Wolverhampton NHS Trust, New Cross Hospital, Wednesfield, Wolverhampton, WV10 0QP, Tel: 01902 695153
- Dr M Moussa, Research Fellow, The Royal Wolverhampton NHS Trust, New Cross Hospital, Wednesfield, Wolverhampton, WV10 0QP, Tel: 01902 695153
- Kate Cheshire, Research Midwife, The Royal Wolverhampton NHS Trust, New Cross Hospital, Wednesfield, Wolverhampton, WV10 0QP, Tel: 01902 307999 Ext. 8395
- Julie Icke, Research Midwife, The Royal Wolverhampton NHS Trust, New Cross Hospital, Wednesfield, Wolverhampton, WV10 0QP, Tel: 01902 307999 Ext. 8395

Alternatively, a local independent contact is:

- Patient advice and liaison service (PALS), PALS office: rwh-tr.PALS@nhs.net or Tel: 01902 695362

Thank you for taking the time to consider taking part in the TIAP study.

Appendix 1: Study Flowchart