Participant Information Sheet

Exploring pregnant women and professional perspectives on use and adherence to oral iron during pregnancy.

Overview

We would like to invite you to take part in a research study looking at how anaemia can be prevented and managed during pregnancy, and specifically the use of oral iron supplements.

WHY ARE WE DOING THIS?

- We want to understand more about how healthcare professionals such as yourself prevent and manage anaemia in pregnant women.
- In particular, we wish to hear your views about management of anaemia and prescribing oral iron supplements for anaemia during pregnancy.
- There are no right or wrong answers and we are interested in a range of perspectives.

WHAT WOULD I NEED TO DO?

- You would need to take part in an interview with a trained researcher lasting approximately 45 minutes.
- This interview would be at a date, time and location that is convenient for you and can be done either in person, via audio/video conference call platforms or over the phone.

WHO CAN GET INVOLVED?

- Healthcare professionals involved in caring for pregnant women such as midwives, obstetricians and General Practitioners (GPs).

Further study information is provided below, as well as contact details for scheduling an interview if you are interested in taking part.

Participant Information Sheet

Exploring patient and professional perspectives on use and adherence to oral iron during pregnancy.

Chief Investigator: Prof. Simon Stanworth

Lead Investigator: Dr Fabiana Lorencatto

INVITATION TO TAKE PART IN A RESEARCH STUDY

We would like to invite you to take part in the above research study. Before you decide if you want to take part or not, we would like to tell you why this study is being done, and what you can expect if you do take part. Please read what we have to say carefully. 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.

WHAT IS THE PURPOSE OF THE STUDY?

Around a third of women in the UK develop anaemia during pregnancy. Anaemia is most commonly caused by iron deficiency. We do not fully understand the consequences of anaemia in pregnancy, but some studies have suggested that in addition to tiredness in the mother, it may be linked to maternal haemorrhage, and infant prematurity.

Currently, we treat women with oral iron supplements if they develop anaemia during pregnancy. However, we want to explore whether we can prevent anaemia during pregnancy, through use of oral iron supplements, and whether this would improve the health outcomes for mother and baby.

This study is the first part of our research programme called 'Primary prevention of maternal Anaemia to avoid preterm Delivery and other Adverse outcomes', or PANDA. This part of the study aims to:

- understand healthcare professionals' (including midwives, doctors, GPs) views on anaemia during pregnancy
- understand healthcare professionals' experience and current practice in managing maternal anaemia and potential methods for preventing anaemia
- understand why pregnant women do or do not start taking oral iron supplements
- develop strategies to help women take oral iron supplements during pregnancy.

To achieve these aims, we want to talk to pregnant women and healthcare professionals to find out what they think about anaemia and why women may or may not take iron

tablets during pregnancy. Their responses will help us to develop a tool to help support women to take iron regularly during pregnancy.

WHY HAVE I BEEN INVITED TO TAKE PART?

We would like to interview healthcare professionals, like yourself, from a range of professional backgrounds, who are routinely involved in the care of pregnant women.

DO I HAVE TO TAKE PART IN THE STUDY?

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. Your line managers and/or colleagues will not be notified of your decision of whether or not you take part.

WHAT WILL HAPPEN IF I DO TAKE PART?

We would like to interview you to ask you a series of questions about how you and your colleagues currently manage anaemia during pregnancy including the use of iron and other supplements. We also want to hear your views about the potential scope for using oral iron supplements to prevent anaemia during pregnancy. There are no right or wrong answers and we are interested in hearing a range of perspectives.

One of our researchers will conduct the interview, which can last approximately 45 minutes, depending on how much you have to say.

We can arrange to talk to you at a place and time that is convenient to you. If you prefer, the interview can be done over the telephone or via an audio/video conference call platform. The researcher will ask you to give consent electronically or in writing in the first instance, and if this is not possible verbally, before the interview to confirm your willingness to participate. With your permission, the interview will be recorded, and a transcript will be produced. If consent is taken verbally, this will be audio-recorded and transcribed for record keeping. The audio-recording will be deleted once a check, written transcript is produced. If you would like, you can be sent a copy of your transcript to review and you will be able to clarify or remove any information.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

We do not anticipate that there are any risks associated with your participation, but you have the right to stop the interview or withdraw from the research at any time. There may be some inconvenience in attending an interview and answering questions, but the interview can be done over the phone or via audio/video conference call platforms if easier for you, at a time and date that suits you.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Your views will help us develop strategies to support management of anaemia during pregnancy and help women to take oral iron supplements as recommended.

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 (GDPR).

NHS Blood and Transplant (NHSBT) is the sponsor for this study and will act as the data controller. This means that we are responsible for looking after your information and using it properly. The sponsor is collaborating with University College London (UCL) and this study will be conducted by researchers from UCL.

An external, UCL approved and GDPR compliant transcription service will transcribe the audio-recorded interviews. A confidentiality agreement will be in place with the transcription service to make sure they maintain confidentiality and security of the information. Those who will be able to view the interview transcript will be limited to the PANDA research team, and the transcription service team. Any information that is used from interviews (for example in published articles), including direct quotes, will be fully anonymised by removing names of people, places and any other identifying information.

The audio recording of the interview will only be accessed by members of the research team. The recording of the interview and data collected from you will be held by the study researchers at UCL, stored on a secure, password protected computer, in a locked office accessed through a swipe locked building. Once a checked, written, anonymised transcripts of the interviews are produced all audio recordings will be deleted. These data about you (e.g. transcripts) will be kept in this secure location for a minimum of 5 years after concluding the study. After this time, it will be destroyed. Paper consent forms will be destroyed within 12 months of completing the study.

In the unlikely event that you disclose anything which we feel puts you or anyone else at risk, confidentiality may need to be broken. We will first discuss with the chief investigator (consultant haematologist), and if required report this to relevant teams, organisations and authorities where appropriate. You will be kept informed at every stage.

HOW WILL WE USE INFORMATION ABOUT YOU?

We will assign your transcript an anonymous participant ID number so that you cannot be personally identified from the data during analysis and reporting of study findings. Anonymised data will be shared with the PANDA research team to enable the analysis to be carried out.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can withdraw your involvement in this study at any time before, during or after the interview, without giving a reason. You are also free to skip over any questions you do not wish to answer, and can answer in as much or as little detail as you would like. Once all of the data has been transcribed and anonymised, the data will be used in the research and withdrawal will not be possible.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about how we use your information in the following places:

- https://www.nhsbt.nhs.uk/privacy/
- by contacting Katrina Smith who is Data Protection Officer and Head of Information Governance for NHSBT - DPO@nhsbt.nhs.uk

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 researcher who is conducting the study or the study lead and/or Chief Investigator (see contact details below).

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

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

At the end of the study, we will analyse results and publish in medical journals and present in other reports and presentations. However, you or your organisation will not be identifiable from the content in these publications and reports. If you want a copy of the results, please notify the researcher interviewing you so that we can send you a copy.

WHO IS ORGANISING THE RESEARCH?

The research is funded by the National Institute for Health Research (NIHR), sponsored by NHS Blood and Transplant (NHSBT) and carried out by a research team from University College London in collaboration with other organisations. These organisations include; University of Oxford, Nottingham University, The Royal Wolverhampton NHS Trust, Imperial College London, and Oxford University Hospitals NHS Foundation Trust.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed and given a favourable opinion by the Health Research Authority NHS Research Ethics committee (Wales REC 1; Reference number 20/WA/0137) and the NHSBT Research & Development Department team.

WHAT HAPPENS NOW?

If you are interested in taking part in this study, please contact the researcher directly (contact details below) or leave your details for the researcher to contact you. The researcher will arrange a mutually agreed time and place to conduct the interview in person, over the phone or via audio/video conference call platforms. The researcher will go through the study information with you and give you the opportunity to ask questions and answer these.

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:

- Dr Elise Crayton (Research Fellow): e.crayton@ucl.ac.uk | Tel: 020 7679 5947
- Dr Fabiana Lorencatto (Study Lead): f.lorencatto@ucl.ac.uk
- Prof Simon Stanworth (Chief Investigator): simon.stanworth@nhsbt.nhs.uk | Tel: 01865381037; NHS Blood and Transplant, John Radcliffe Hospital, Oxford OX3 9BQ

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