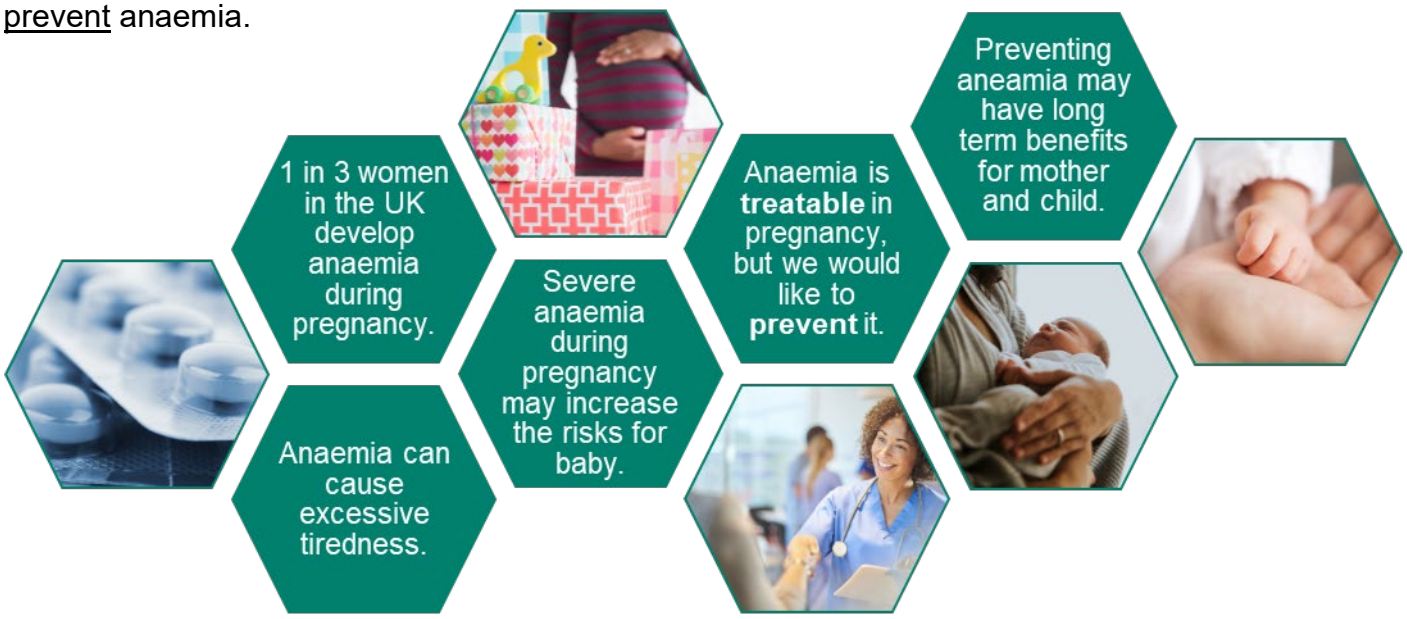
PARTICIPANT INFORMATION SHEET

Before you decide, it is important for you to understand why the research is being done, what it will involve from you, and the type of data to be collected about you and your baby.
Please take your time to read this information sheet carefully.
*Whether or not you wish to take part is **entirely up to you**. Feel free to talk to others, such as health professionals, family, or friends; and contact us if you need more information.*

What is PANDA?

Primary prevention of maternal **AN**aemia to avoid preterm **D**elivery and other **A**dverse outcomes. Currently, pregnant women are treated for anaemia when it shows up on a routine blood test. We (the PANDA research team) want to understand if taking iron supplements earlier in pregnancy can prevent anaemia.



Women with experience of anaemia and maternity services support this research. Their experiences have been considered throughout the planning of this study.

Who can take part? Pregnant women aged 18 or over, who do not have anaemia.
Including a wide range of people is important to ensure the results are relevant for as many women and babies as possible.

Why have I been invited to take part? This maternity unit is supporting PANDA and approaching pregnant women to take part in this study.

What are the benefits of taking part? We are trying to find out whether routinely taking iron tablets may help to prevent anaemia. At this stage, we do not know whether this will be helpful and the only way we can find out is by doing this study. We do not know whether there will be any benefits for you or your baby. The information we gain from this study will help us to give the best possible maternity care in the future.

What are the risks of taking part? We believe taking part in this study doesn't put you or your baby at any risk. We will always prioritise the health of you and your baby. If you develop anaemia during the trial, you will be offered treatment.

If you decide you would like to take part, please inform your care team or contact the research team directly. The research team will arrange to meet with you to go through the study information and give you the opportunity to ask any questions. If you are still happy to proceed, the team will then ask you to provide written consent.

Telephone: ***Site number*** **Email:** ***site email***

We want to prevent the risks caused by anaemia during pregnancy

We will always prioritise the health of you and your baby.

What's involved?

Everyone will get their usual maternity care. Taking part in the trial will not change or impact the care provided by your doctor, midwife, and other healthcare providers. If you develop anaemia during the trial, you will be offered treatment.

You will be randomly allocated (like tossing a coin) to take either iron tablets or a placebo ('dummy' tablets) every day from when you join the study until 6 weeks after delivery. This is a double-blind study so neither you nor the team looking after you knows which group you are in. You will be offered reminders about taking your tablets. There will be 3 short questionnaires at 28 weeks of pregnancy and three, 5-minute questionnaires at 6 weeks after birth, all online.If you become anemic during the study an additional one of these questionnaires will be completed with you after your initial treatment. You will be asked when and how the team should make contact, and your contact details for text messages and emails. You will also be asked if you would like to take part in an interview about your experience of taking part in the PANDA study and receiving reminders to take your study tablets as recommended. This interview will take place at the end of the study. One of the questionnaires contains questions which may be deemed as sensitive.

Research data gathered about you and your child:

You need to understand how your data will be used so that you can provide informed consent. We have listed some details about data collection below, and the details of how to contact the researchers are at the end of this information sheet if you have any questions.

Some of the data collected will be:

- ✓ **Personal contact details & postcode**
- ✓ **Your due date**
- ✓ **General health and wellbeing**
- ✓ **Iron levels from routine blood tests (no additional blood samples)**
- ✓ **Your baby's birthdate**
- ✓ **Baby's birth weight**

In addition to data that we gather directly from you and your child, we would also like to access national databases of routinely collected data that would include information about visits to the hospital, test results, and treatment for you or your child. We may also access data held about your child's health, educational achievements, and mental health to link with data from the PANDA study for up to 16 years.

We will use your and your child's NHS/CHI number, date of birth and postcode to link with other organisation systems to collect data on admissions to hospital and the treatment you or your child received, information on mental health, and assess if there are any long-term benefits to be gained for you or your child. They are databases that hold routine data about everyone securely. The health datasets are the Hospital Episodes Statistics (HES) from NHS England , and the Office of National Statistics (ONS) in England, the Secure Anonymised Information Linkage (SAIL) database for residents of Wales and the electronic Data Research and Innovation (eDRIS) database for residents of Scotland. We will collect data from the National Neonatal Research Database if your child was admitted to a neonatal unit including information about the treatment they received. We will collect data on their development up to 2 years of age. We will also request information from the National Pupil Database which keeps records of a child's educational progress up to the age of 16.

It is important that you know that as part of the long term follow up of the study we will not be contacting you or your child for this data. It will all be obtained from the databases using your personal identifiers

Interviews – If you consent to take part in an interview you may be contacted by one of the PANDA behavioural science research team from University College London (UCL). The interview will be scheduled at your convenience and held remotely. You will be asked some questions on your experience in the study and the support you received. This interview will be recorded and transcribed using an approved professional transcribing service before being analysed by researchers from University College London. Only a small number of women will be asked to take part in an interview.

All PANDA work will be done in line with the UK General Data Protection Regulation (GDPR). Data protection regulations ask us to tell you the legal basis for processing information about you. This research is 'a task in the public interest.' NHS Blood and Transplant (NHSBT), the Sponsor of the trial, is the data controller (as defined in GDPR) and is responsible for looking after your information and using it properly.

Questions and Answers about the PANDA trial

Can anybody take part?

- A member of the research team will check your medical history to ensure it's safe for you to take part and your health will be monitored throughout your pregnancy by your care team
- You can take part if you are planning birth in a hospital maternity unit or midwifery unit or at home.
- You cannot take part if you have been found to be anaemic and have been prescribed iron tablets or any other treatment uncluding intravenous iron and blood tranfusions.
- If you are taking an iron supplement not prescribed by a healthcare professional you can still continue to take it, if you wish.

What are the known side effects from taking iron?

- Possible side effects include lack of appetite, abdominal pain, nausea, vomiting, constipation or diarrhoea, dark stools, mouth ulcers.
- If you experience some of these effects, the **local research team** may be able to provide you with medicine/advice to help with these side effects AND OR reduce the dose of iron you take.

What if I am found to be anaemic?

- If you are found to be anaemic during the trial, you will be offered treatment and advice in line with the usual care.
- We will also collect this treatment data to determine the type of treatment and initial response to it.

What if I want to stop or complain?

- If at any stage, you have concerns about the study or the way it has been carried out, please talk to someone as soon as possible.
- You can contact the PANDA team, either the researcher who is conducting the study or the study lead or Chief Investigators - details below.
- You can also talk to your midwife or your doctor.
- The Patient Advice and Liaison Service (PALS) in the hospital*: [insert local NHS Trust name, PALS email and telephone number, and website if available].*
- If you remain unhappy and wish to complain formally you can do this through the NHS complaints procedure.

What if there is a problem?

- **You can stop at any point, without giving a reason -** You will no longer receive the study treatment, but NHS care will continue.
- We will ask if you are willing to allow us to collect data about your delivery and infant.
- You can request for your identifiable data to be removed, however, all anonymised data already collected up to that point will continue to be used in the research. This is because NHSBT needs to manage your information in specific ways to keep the research reliable and accurate.

Please bear with us with the legal jargon and details in this section Feel free to test us with questions if any of it is unclear!

How will we use information about you?: NHSBT will be using information from you and your medical records in this trial and will use the minimum personally identifiable information possible.

This information will include::

- Your name
- Your and your child's NHS/CHI number
- Your and your child's postcode
- Your and your child's date of birth
- Your email address and phone number

We will use this information to do the research, contact you for follow up and to check your records to make sure that the research is being done properly. Your local study team will share your email address and phone number with the PANDA central research team at NHSBT so that they can contact you directly to send you texts, reminders to take your tablets and information about the trial, as well as to ask you to complete the questionnaires and take part in an interview. NHSBT will keep identifiable information (e.g. your NHS number, baby DoB etc.) about you and your child until the trial has finished and all data has been collected. This excludes any research documents with personal information, such as consent forms, which will be held separately and securely for at least 15 years after the end of the study. The interview recordings and transcripts will be stored by UCL until deleted.

We will encrypt all your data to keep your identity, and that of your baby, safe.

People who do not need to know who you are will not be able to see your name or contact details. Your information, including the study questionnaires, blood test results, your email address and phone number, and other medical information needed for the trial will be uploaded to a secure trial database with limited access. A code, called a trial number, will be used to label your data. At the end of the trial, your information alongside your trial number will be used for analysis. PANDA investigators at NHSBT and their selected research partners will be able to see and analyse this de-identified information.

You can find out more about how we use your information at https://www.nhsbt.nhs.uk/privacy/ or www.hra.nhs.uk/information-about-participants/ or by contacting:

- Data Protection Officer for NHSBT informationgovernanceteam@nhsbt.nhs.uk.
- By asking one of the research team, please refer to details on page 2. Or
- by sending an email to PANDA@nhsbt.nhs.uk

We believe that taking part in this study doesn't put you at any risk, however NHSBT will provide indemnity for this study.
There are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial because of negligence on the part of a member of the study team this liability cover would apply. Non-negligent harm is not covered by the NHS indemnity scheme. NHSBT, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

What are your choices about how your information is used? You can stop taking the study tablets at any time, without giving a reason. If you choose to stop, we would still like to continue collecting information from your and your child's health records and from the databases mentioned in this information sheet. If you do not want the collection of data to continue after you have stopped taking the tablets, please make contact to tell us and we will stop. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you, and we are required to keep any information about you that we have already collected.

Who has reviewed the study?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and approved by the Health Research Authority NHS Research Ethics committee (23/NS/0123) and the NHSBT Research & Development Department team.

What will happen to the results of the study?

Reports will be published through the National Institute for Health Research (funder), medical journals and the PANDA website. Summaries will be prepared for participants and member of the public.

The research is led by Professor Simon Stanworth (Consultant Haematologist for NHS Blood & Transplant (NHSBT) at the John Radcliffe Hospital, Oxford) and Professor Marian Knight (NIHR Professor of Maternal and Child Population Health). The research is funded by a National Institute for Health Research Applied Programme Grant.
All members of the research team are listed here (or type the following into your browser: https://bit.ly/3twtsD8)

Thank you for taking time to consider being part of this study.