PARTICIPANT INFORMATION SHEET

Project Title: Investigating the effects of iron on the gastrointestinal tract in health.

IRAS Reference:

Section A: The Research Project

Purpose of the study: This study is part of a PhD at Anglia Ruskin University.

Supervisors: Dr Rudolph Schutte, Professor Selim Cellek and Dr Anthony Hobson

Chief Investigator: Dr Anthony Hobson (Anthony@thefunctionalgutclinic.com)

Main Investigator: Sarah Bloor (SRS170@pgr.aru.ac.uk)

Why have I been asked to participate?

We'd like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you.

You may be suitable to participate if you are healthy and willing to take an oral iron supplement, ferrous sulphate, to compare the changes to your gut bacteria after 28 days of supplementation.

We'd suggest you should take atleast 24 hours to consider the information about the study. Please feel free to talk to others about the study if you wish.

The first part of the participant information sheet tells you the purpose of the study and what will happen if you decide to take part.

Then we give you more detailed information about the conduct of the study and how your data is handled.

Brief summary of research:

Over recent years there has been a lot of research looking at how the bacteria in our gut affects our health. Some medications are known to cause changes in gut bacteria.

Many patients that are prescribed iron report gastrointestinal side effects. This research project aims to see if the cause of the gastrointestinal side effects is due to iron causing changes in the gut bacteria. This can be detected via measuring the levels of hydrogen and methane and other compounds in the breath and stool.

How many people will be asked to participate?

This study has been designed to enrol 48 participants.

What are the likely benefits of taking part?

This project will evaluate the effect of oral iron supplements on the gut bacteria of healthy individuals.

Taking part will not have any direct benefit to yourself but will assist with the advancement of knowledge into the effects of oral iron supplements on gut bacteria and gut health.

Will it cost me anything to take part?

This study will not cost you anything to participate in.

Can I refuse to take part?

At any point of the study, you can refuse to take part without giving a reason.

Has the study got ethical approval?

This study has been approved by the London Surrey Borders Research Ethics Committee (REC) and Anglia Ruskin University Faculty Research Ethics Panel.

Has the organisation where you are carrying out the research given permission?

Yes

Source of funding for the research project: The Functional Gut Clinic

What will happen to the results of the study?

The data collected will be aggregated and results of the research project will be written up for a PhD thesis, published in journals and presented at conferences.

Contact for further information

If you require any further information, or have any questions about this research project then please contact Sarah Bloor on SRS170@pgr.aru.ac.uk

Section B: Your Participation in the Research Project

What will I be asked to do?

Once you have read through the participant information sheet, please contact SRS170@pgr.aru.ac.uk to ask any questions you may have and if you would like to proceed you will be sent a pre-screening questionnaire. You can either complete this screening questionnaire at home and send it back to the main investigator or relay your answers over the phone to the main investigator.

If you meet all the criteria, including non-pregnancy confirmed with a pregnancy test, and are happy to go ahead with the study, you will be asked to attend for your first study visit.

You will be first asked to complete a consent form and then you will be fully enrolled into the study. You will then be asked to provide a stool sample, complete a 3hr breath test and answer some questionnaires. The questionnaires will ask about your gut health, diet and lifestyle and should take approximately 10-20 minutes to complete.

After 28 days (+/- 2 days) of taking oral iron supplements you will be asked to attend for your final visit to provide a stool sample, complete a 3hr breath test and answer a questionnaire on gut health. We will also ask you if you experienced any side effects.

For the 4 week duration of the study you will be asked to complete a daily diary relating to your tummy, bowel habit and if you have taken your oral iron supplement. This should take no more than 2 minutes per day. The diary has a page for week 5 for participants who continue taking the oral iron supplement into day 29 and day 30. This circumstance will only arise if the participant is unable to attend for their end of study visit on day 28.

Summary of study visits

1. Eligibility screening – (verification of health status with health questionnaire) – this questionnaire will take approximately 5-10 minutes to complete.
2. Day 1 – Enrolment visit: stool sample collection + 3hr breath test + gut health, diet and lifestyle questionnaires. This visit will last approximately 3.5 hours.
3. Day 28 (+/- 2 days) – Final visit: stool sample collection + 3hr breath test + gut health questionnaire + compliance verification. This visit will last approximately 3.5 hours.

Giving a stool sample

Stool samples will be collected using a FeelGut testing kit at the Functional Gut Clinic in Manchester, Cambridge or London.

The procedure for giving a stool sample will be explained to you prior to your enrolment into the study by a member of the study team.

Completing a breath test

You will visit the Functional Gut Clinic Manchester, Cambridge or London for a hydrogen and methane breath test (HMBT) along with supplementary volatile organic compound analysis.

On the day before this visit (day 0) you will be asked to complete low fibre diet for the breath test to be accurate. More information on the preparation will be provided in advance of your visit.

The HMBT is a simple non-invasive test which takes around 3 hours to complete. During the test you are required to blow into a test tube every 15 minutes and asked to drink a sugary (lactulose) solution.

To provide a breath sample for volatile organic compound analysis, a mask attached to a handheld device will be held against your face and capture your breath as you breath in and out normally.

There are no risks or side effects associated with this test.

Will my participation in the study be kept confidential?

If you give permission to, we will inform your GP about your involvement in this study.

Participation in the study will be kept anonymous and only members of the research team will have access to the data in an anonymised format.

The results will be written up in an anonymised format. Participant's personal data will not be included in the dissemination of the findings.

Will I be paid for my participation?

£250 for participant compensation will be given for full participation within the trial, to cover time and travel expenses. This will be given following completion of the final breath test and stool sample and confirmation of compliance to the study. For those unable to complete the full study, travel expenses will be given for travel incurred up to the point of dropping out of the study.

Are there any possible disadvantages or risks to taking part?

Oral iron supplements are tested products available on the market and manufactured to pharmaceutical standards. The product is provided in small tablets so there is minimal choking hazard.

Like all medications, oral iron supplements can cause side effects although not everybody gets them. This may include change in bowel habit, feeling sick and blackened stools.

The agreement to participate in the study does not affect participant's legal rights.

Can I withdraw at any time, and how?

Participants can withdraw from the study at any time and without giving a reason by emailing SRS170@pgr.aru.ac.uk. Participants that withdraw from the study will be asked if they are happy for anonymised data collected up to that point to be used or if they would like to have their data removed.

The last approximate time it will be possible to withdraw their data will be fourteen (14) days after the final visit. Participants should also be aware that they do not have to answer any question asked in a questionnaire they do not want to.

Are there any special precautions that must be taken before, during or after taking part in the study?

Participants should follow the specific diet and fasting period before attending the clinic for the breath test. There are no other special precautions that must be taken before, during or after taking part in the study. Participants should try to minimise changes to their diet and lifestyle throughout the study.

What will happen to the information and samples that are collected from you?

Information collected from participants will be securely held at the Functional Gut Clinic until the end of the PhD project, marked by the acceptance of the PhD thesis.

This information will include your name and contact details. People will use this information to do the research, contact you if needed, and check your records to ensure that the research is being done correctly. 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.

Only those people who are authorised from The Functional Gut Clinic and Anglia Ruskin University to do so will have access to your information. This will include the chief investigator, the main investigator, the PhD supervisors and the sponsor contact.

We will keep all information about you safe and secure.

Confidentiality/data protection procedures for all the data collected in the screening forms for those deemed ineligible (name/age/past medical history) and subsequently don't sign an informed consent form will be followed as for the rest of the study data.

For analysis of the stool samples, some of your information will be sent to ADM Lifesequencing in Spain. They will not be able to see your name or contact details and your data will have a code number instead. They must follow our rules about keeping your information safe

Once we have finished the study, we will keep data about your age and gender so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Breath samples collected will be analysed and then destroyed, with only the data from analysis being kept.

Faecal samples collected will be analysed and then destroyed, with only the data from the analysis being kept.

Summary of research findings

Research findings will be published as a part of a PhD thesis, in journal articles and presented at conferences.

All participants will receive a copy of the published journal article, if an email address is provided.

Contact details for complaints

Participants that have any complaints about the study should contact SRS170@pgr.aru.ac.uk , anthony@thefunctionalgutclinic.com or rudolph.schutte@anglia.ac.uk in the first instance.

For Anglia Ruskin University's complaints procedure, please contact;

Email address: complaints@anglia.ac.uk
Postal address: Office of the Secretary and Clerk, Anglia Ruskin University, Bishop Hall Lane, Chelmsford, Essex, CM1 1SQ.

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