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University Hospital Southampton NHS
NHS Foundation Trust

University of Southampton

Influence of soluble corn fibre on markers of immunity and inflammation

Information Sheet for Study Participants

REC Reference number 22/SC/0414
CRF Study ID:

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You are being invited to take part in a research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or if you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

SUMMARY

This research study is being organised by the Faculty of Medicine at The University of Southampton. The research is being funded by Tate and Lyle, a company that produces soluble corn fibre for use in the food industry. The University of Southampton is acting as the legal sponsor of the study. The study has been reviewed and approved by the South Central Hampshire Research Ethics Committee.

Most people in the UK do not eat enough fibre. We plan to investigate whether fibre supplements improve measures of the immune system, inflammation and intestinal bacteria. The fibre supplement we will use will be soluble corn fibre. We will compare the effects of using soluble corn fibre each day for 12 weeks with the effects of a placebo ("dummy"). Both the fibre and the placebo will be provided as powders in a sachet that can be stirred into a glass of water or orange juice. For the study we will enrol 72 healthy men and women over the age of 60 years. If you are enrolled you will allocated randomly to the fibre or placebo group and you will not know which one you are taking. Of course, you do not have to take part and before you decide to do so or not we will explain the study to you fully. If you decide to take part you will sign a consent form.

If you decide to take part, you will be asked to attend 2 appointments at the Clinical Research Facility at Southampton General Hospital. For both appointments, you will come in the morning before you have had your breakfast. You will be asked to fast ahead of your visit (no food or drink apart from water from 9 pm the night before). You will receive breakfast during your visit.

At the first visit we will discuss the study with you and if you are happy, you will give your written consent to participate in the study. We will measure your height, weight and blood pressure. We will then take some blood (~30 ml; about 1.5 tablespoonfuls) and you will complete questionnaires asking you about your diet (food frequency questionnaire) and gut health (GI questionnaire and The Bristol Stool Chart). You will be asked to provide a urine sample. This appointment will last 1-1.5 hours. You will be provided with breakfast after we have made the body measurements and collected your blood. You will be given a collection kit to take away with you to collect a faecal (poo) sample at home. You will receive instructions on how to do this and how to store your sample. This sample should be provided before you start taking any study supplement. We will arrange for a courier to collect the samples from you at home. The courier will need to know your name, address and phone number.

The second visit will take place about 12 weeks after the first visit. The second visit will be the same as the first one, except that you will not be required to give your consent. Between the first and second visits you will take your supplement daily and you will record this in a paper diary that we will provide you with. You will be contacted by the research team every 4 weeks but you will be able to contact the

team yourself at any other point also.

Your blood, urine and faeces will be treated anonymously and will not be able to be linked directly to you. Blood samples will be analysed in our own laboratories at University Hospital Southampton and University of Southampton for markers of immunity and inflammation. Urine samples will be stored for future analysis of chemicals produced by the gut microbiota. Samples will be analysed in our own laboratories at University of Southampton. Faecal samples will be stored for analysis. Samples will be analysed in our own laboratories at University of Southampton for fatty acids and sent to our partner at Catholic University of Louvain, Brussels, Belgium for identification of the gut bacteria. These samples will be marked with an ID number and will not be linked to your name.

We will hold your contact details for the duration of the study, but these will be destroyed at the end of the study.

Your participation and the information we collect about you during the course of the research will be kept strictly confidential. You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected.

On completion of the study your travel expenses will be reimbursed.

What is the research about?

As we age, our immune system becomes weaker and there is an increase in inflammation which contributes to common age-related diseases. These include heart disease, metabolic disease such as type-2 diabetes, the loss of muscle mass and strength known as sarcopenia, the weakening of bones known as osteoporosis, some cancers, and possibly dementia. A weaker immune system means older people can be more susceptible to infections and that some vaccines may not work as well as in younger adults.

The “healthy” bacteria in our intestine (called gut microbiota) have an influence on our immune system and our inflammation. Our intestinal bacteria also change with ageing and this can result in the loss of protective function and in the movement of harmful bacterial toxins and whole bacteria from the gut into the blood. Why these changes occur and how we can improve this in ageing are not understood. What we do know is that our intestinal bacteria can be altered by our diet. Fibre intake is considered essential for optimal gut health including maintaining healthy gut bacteria. However, most people do not eat enough fibre. We plan to investigate whether fibre supplements improve measures of the immune system, inflammation and intestinal bacteria. The fibre supplement we will use will be soluble corn fibre. Soluble corn fibre resists digestion and absorption in the small intestine and passes to the large intestine where it can be fermented (used) by the gut microbiota. Soluble corn fibre has been shown to beneficially modify gut microbiota but its effects on the immune system and inflammation have not been tested in older people.

We plan to compare the effects of using soluble corn fibre on the immune system and inflammation and gut microbiota with the effects of a placebo which is a poorly digested sugar called maltodextrin.

Why have I been asked to participate?

You have been contacted because you have expressed an interest in our research by answering our advertisement and you appear to meet the inclusion criteria. We need healthy men and women over the age of 60 years. We will be recruiting 72 participants in total.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form. However, you will still be free to withdraw at any time, and without giving a reason. If you do withdraw, we will use any data we have already collected from you (anonymously) but you will be asked whether you want us to destroy any samples you have given as part of the study.

What will happen to me if I take part?

If you decide to take part, you will be asked to attend 2 appointments at the Clinical Research Facility at Southampton General Hospital.

At both appointments, you will come in the morning before you have had your breakfast. You will be asked to fast ahead of your visit (no food or drink apart from water from 9 pm the night before). You will receive breakfast during your visit.

At the first visit we will discuss the study with you and if you are happy, you will give your written consent to participate in the study. We will measure your height, weight and blood pressure. We will then take some blood (~30 ml; about 1.5 tablespoonfuls) and you will complete three questionnaires asking you about your diet (food frequency questionnaire) and gut health (GI questionnaire and The Bristol Stool Chart). You will be asked to provide a urine sample. This appointment will last 1-1.5 hours. You will be provided with breakfast after we have made the body measurements and collected your blood. You will be given a collection kit to take away with you to collect a faecal (poo) sample at home. You will receive instructions on how to do this and how to store your sample. This sample should be provided before you start taking any study supplement. We will arrange for a courier to collect the samples from you at home.

The courier will need to know your name, address and phone number.

You will be allocated to one of two treatment groups. You will be provided with either 20 grams/day of corn fibre or a daily placebo supplement for 12 weeks (3 months). This allocation will be randomised and 'blinded' so you will not know which supplement you are consuming. The corn fibre and placebo will be powders provided in a sachet. They are both tasteless. You will be able to stir the powder into a glass of water or orange juice.

Between the first and second visits you will be asked to record the daily ingestion of your supplement in a paper diary that we will provide you with. You will be contacted by the research team every 4 weeks but you will be able to contact the team yourself at any other point also.

The second visit will take place about 3 months after the first visit. At the second visit we will take a second set of body measurements and collect another ~30 ml blood sample. You will then be asked to complete a final set of questionnaires; these will be the same ones as used at the first visit. The second visit will again last about 1-1.5 hours. Again, you will receive breakfast during your visit. You will be given another collection kit to take away with you to collect a faecal (poo) sample at home. You will receive instructions on how to do this and how to store your sample. This sample should be provided as soon after the clinic visit as possible. We will arrange for a courier to collect the samples from you at home.

Your blood, urine, and faeces will be treated anonymously and will not be able to be linked directly to you.
Blood samples will be analysed in our own laboratories at University Hospital Southampton and University of Southampton for markers of immunity and inflammation.

Urine samples will be stored for future analysis of chemicals produced by the gut microbiota. Samples will be analysed in our own laboratories at University of Southampton.

Faecal samples will be stored for analysis. Samples will be analysed in our own laboratories at University of Southampton for fatty acids and sent to our partner at Catholic University of Louvain, Brussels, Belgium for identification of the gut bacteria.

These samples will be marked with an ID number and will not be linked to your name.

Any faecal samples left over at the end of the study will be destroyed. Any blood or urine samples left over at the end of the study will be transferred to a research biobank for future use if you consent to this. If this happens, a record linking the ID number on the samples to you will be kept in a secure location.

What do I have to do?
You will attend Southampton General Hospital for 2 visits. Each visit will last 1 to 1.5 hours. You will be asked to answer a set of questions about your diet and gut health at each visit. In between the two visits you will be asked to complete a daily paper diary to record ingestion of your supplement. You will speak with the research team every 4 weeks. The visits will take place over a period of about 3-5 months. You will be asked to provide blood, urine and faecal samples. You will be given collection kits for the faecal samples to be collected at home and you will be asked to complete a sample collection log.

What are the benefits of taking part?
You may benefit from positive effects to your immune system and/ or your intestinal bacteria. Knowledge gained from this study will help our research and will ultimately be of use to other researchers and consumers.

What are the possible disadvantages and risks of taking part?
You will probably be familiar with providing blood for tests or for donation. With any procedure involving blood collection with a needle, there is a very small chance of infection and a chance of bleeding and bruising at the site of insertion of the needle. This will be minimised by using sterile techniques and trained members of staff.

What data will be collected?
We will hold your contact details for the duration of the study, but these will be destroyed at the end of the study.

We will collect information about your age, sex, height, weight and general health. This will be collected by research staff. We or our research partners will measure chemicals in your blood and urine, and investigate your intestinal bacteria from your faeces, that will tell us about your immune system, level of inflammation, gut health, and metabolism. We will collect information about your diet. All personal data will be kept in a locked filing cabinet and on a password protected computer. No data will be linked with your name and address, only to an anonymous study code.

Will my participation be confidential?
Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you. This is for monitoring

purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Do I have to take part?
No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

What happens if I change my mind?
You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights (or routine care if a patient) being affected. You can withdraw by informing the research team. If you withdraw we will use any data (anonymously) that we have already collected from you but if you do not wish us to use your samples, then they will be destroyed.

What will happen to the study results?
Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

The results may be presented at scientific meetings and published in a scientific journal. You will not be identified in any of these presentations or publications.

We will be happy to discuss the results with you when the study is completed and will let you know where you can obtain a copy of the published results.

If we find that any of the measurements made on your samples show abnormal values we will provide you with a note explaining this for you to take to your GP.

Will I be reimbursed for my time?
On completion of the study your travel expenses will be reimbursed.

Who is organising and funding the study?
This study is being organised by the Faculty of Medicine at The University of Southampton. The research is being funded by Tate and Lyle, a company that produces soluble corn fibre for use in the food industry. The University of Southampton is acting as the legal sponsor of the study.

Who has reviewed the study?
The South Central Hampshire Research Ethics Committee.

What will happen if anything goes wrong?
If something goes wrong during an investigation day any procedures will be stopped and you will be seen by a doctor. Your involvement in the rest of the study may be stopped.

If you have a concern about any aspect of the study you should speak to the researcher involved who will do their best to answer your questions (telephone 077 2610 0436). If you remain unhappy and wish to complain formally you should contact the NIHR Clinical Research Facility in the first instance (telephone 023 8079 4989). Any complaint about the way that you have been dealt with during the study or any possible harm you might suffer will be addressed.

You may also contact the University of Southampton Head of Research Integrity and Governance at rgoinfo@soton.ac.uk.

The study is covered by insurance held by the University of Southampton. This insurance covers the possibility of compensation should anything go wrong during the study.

What precautions are in place regarding Covid-19?
The Clinical Research Facility is inside Southampton General Hospital Southampton. It is a short distance from the main entrance and is only accessed by individuals and staff working in the facility or attending clinical trial appointments. As with all areas of the hospital, enhanced sanitisation is in place and face masks/coverings are currently mandatory. There are a number of hand sanitisation points along the short walk to the research facility within the hospital and social distancing is maintained by staff where possible. Appropriate PPE including gloves and aprons are routinely worn by staff for all sample collections, with the addition of face coverings during this time.

Data Protection Privacy Notice
The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for one year after the study has finished. After this time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Contact for further information

If you have any further questions then please contact Ella Baker at The Faculty of Medicine, University of Southampton on 07849785508 or e-mail E.baker@soton.ac.uk

And finally…

Thank you for having taken the time to read this information sheet and for your interest in the study. If you do decide to take part in the study, you will be given a copy of this information sheet and a signed consent form for you to keep. You should keep this sheet for at least as long as you are participating in the study.