The beetroot study

Information sheet for study participants

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Participant Information Sheet

Title of project: Bioavailability of phenolic compounds, betalain and inorganic nitrate following incremental portions of whole beetroot in older and younger adults.

You are invited to participate in this dietary intervention study. Please take time to read the following information carefully. It explains why the research is being done and what it involves. If you have any questions about the information, please just ask for further explanation. Thank you for reading this. Discuss with others if you wish and please take time to decide whether you would like to take part.

PART 1

What is the purpose of the research project?

Ageing has an effect on many systems in the body, including the ability to breakdown and utilise compounds within food. Beetroot is rich in nitrate and polyphenols, and these can have beneficial effects on the body. Younger and older adults however, may process these compounds differently and therefore their beneficial effects can be attenuated. The aim of this study is: 1) to assess the availability of compounds following consumption of beetroot or a dose of inorganic nitrate 2) to assess the effect of these compounds on vascular function

Why have I been chosen?

You have been chosen because you are healthy and of a suitable age to take part in this study. The project will involve 30 participants in total.

Do I have to take part?

Your participation is entirely voluntary and all results will be strictly anonymous. If you decide to take part you are still free to withdraw at any time without reason and without your medical care being affected. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

What will the research project involve?

We will contact you by phone to answer any questions you may have about the study. We will then ask you some questions about your medical history to check whether you can participate. You will not be included in the study if you have any medical conditions or are taking medications that will affect the measurements in the study. If you are a suitable participant, you will be invited

to attend the Clinical Research Facility (CRF) at the Royal Victoria Infirmary where the study will take place.

Initial screening: You will arrive at the CRF for an initial screening visit, which should take no longer than 45 minutes. We will go through the participant information sheet and answer any questions. After having had time to make a decision, you will be asked to sign a consent form stating that you would like to take part in this research study. We will go through a short medical history questionnaire, measure your height and weight to calculate your BMI, and will take a resting blood pressure measurement. These results will be needed to decide whether you can be included in the study or not. If your BMI and blood pressure readings are outside a specific range, you will not be able to take part in the study. The visit will then conclude by taking a blood sample, which will amount to about two teaspoons in volume. We will provide you with all the information and materials necessary to continue the study. You will be asked to attend the CRF on a further four occasions, separated by around seven days, for further testing. Before each of the four visits, you will be provided with an evening meal to consume the day before. You will be asked to follow a restricted diet in the two days leading up to each visit and on the day before the first visit we will ask you to collect urine samples. You will also be asked to refrain from using anti-bacterial gum and mouthwash for the duration of the study.

Study visits: You will attend the CRF in the morning and your blood pressure, blood flow and anthropometric measurements will be taken, along with a blood, urine and saliva sample. You will be given breakfast and will then be asked to consume a set amount of beetroot (100g, 200g or 300g) or will be given a dose of potassium nitrate in a solution. Over the next 5 hours, blood pressure, blood flow, and blood, urine and saliva samples will be taken at regular intervals. You will be fitted with a cannula for blood samples, which may cause slight discomfort when initially inserted but should be painless once in place. After the last sample has been taken, you will receive lunch and will then be free to leave. You will be provided with your evening meal to consume for that day and some sample pots to measure your urine and saliva over the following 12 hours. This protocol will be repeated on the following three visits. During the study you will be asked to complete a food diary, physical activity questionnaire and complete a survey to assess your enjoyment of the beetroot provided.

Measurements and samples taken

10ml of blood (about two teaspoons) will be taken at seven time points during the visit, to analyse the compounds in the blood following beetroot or potassium nitrate consumption. 70ml of blood will be taken in total for each visit. Blood samples will be taken using a cannula that will be inserted into your arm for the entirety of the visit. You will also be asked to provide urine and saliva samples at similar time points, which will involve simply depositing a sample into a designated container. Your blood pressure will be measured using an inflatable

cuff similar to the one used in GP surgeries. We will measure your blood flow at the start, middle and end of the testing period, using a non-invasive technique called post-occlusive reactive hyperaemia. This will assess whether the beetroot or potassium nitrate that you consume has any impact on the width of your blood vessels and how much blood flows through them. The final measurement will be the amount of nitric oxide that you exhale in your breath, called fractional exhaled nitric oxide (FeNO). Everyone exhales nitric oxide normally but we know that the amount you exhale can be influenced by diet and the amount of nitrate consumed. We will measure your FeNO at seven time points throughout the visit by asking you to breath into a handheld sensor.

Expenses and payments

You will receive a one-off voucher worth £100 on completion of the study, as long as you have completed all four visits, as compensation for your time. In addition, some meals will be provided the day before and day of each visit. Reasonable travel costs to and from the CRF will also be covered.

What do I have to do?

You will be asked to follow a low-nitrate and low-polyphenol diet for the two days leading up to each study visit and your evening meal will be provided on the day before each visit. A list of foods and beverages to avoid will be provided. You will also be given breakfast and lunch when attending the CRF on each day and will be provided with a meal to consume at the end of the visit day.

What data do I need to supply?

We will require your name and address or email for correspondence and for transport. Your details will not be linked to that data collected during the study. We will require your age to determine your eligibility for the study and will ask you for details of your medical history during a telephone screening call.

What are the side effects of the treatment when taking part?

Consumption of beetroot can cause beeturia, turning your urine and/or stool a red or pink colour. This is harmless and completely normal.

Are there any other possible disadvantages of taking part?

Giving up time to participate must be considered. We will be taking blood from a vein in your arm by inserting a cannula and it is possible that you might experience slight discomfort when it is being placed in the arm and/or bruising when it is taken out. You will be asked to follow a restricted diet in the run up to testing, which may be very different to your normal diet.

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What are the possible benefits of taking part?

Beetroot counts towards your 5-a-day, so you will be giving your day a small health boost. Beetroot has also been found to acutely reduce blood pressure, which has many benefits to health. You will have your height, weight, waist circumference and body fat percentage measured, which are useful to know.

What happens at the end of the research project?

At the end of the project, we will be able to inform you of the results of the study. Results will be presented with the intention to publish in scientific journals. All results will be presented as grouped data and your individual results will not be identifiable.

What if there is a problem?

If you have a concern or complaint about any aspect of the study, Prof Emma Stevenson will deal this with immediately. You can contact her on 0191 208 7865 or write to her at the address detailed below. Medical staff are always on hand in the Clinical Research Facility.

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454
Email: patient.relations@nuth.nhs.uk
Address: Patient Relations Department, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Freeman Hospital, Newcastle upon Tyne, NE7 7DN.

Will my taking part in the project be kept confidential?

Yes, we value your input to this project and all data gathered from you will be treated in the strictest of confidence. Only members of the research team will have access to the data, which will be stored for 5 years, and the results will be anonymous so you cannot be directly identified. Also, although the results may be published, your data will be compiled with others and available as an average, so again you cannot be identified.

What will happen to the results of the research study?

You will not be identified in any report or publication. You will be given a copy of the results once they are published if you wish.

Who has reviewed the study?

This study has been internally reviewed by the research team at Newcastle University and ethical review of the study has been conducted by East of England – Cambridge Central Research Ethics Committee.

Who are the contacts for further information?

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PART 2

What if relevant new information becomes available?

If new information is published during the course of a study, this can sometimes change how the research should go forward. If this happens, you will be notified immediately and the study will be altered accordingly.

Will anyone else know that I'm doing this?

We will inform your GP that you will be taking part in this study. Only members of the research team will have access to the data. All information that is collected during this research study will be kept strictly confidential and your name and address will be removed so that you cannot be recognised from it. Any information you give or data collected will be retained for a maximum duration of 5 years.

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

You will be able to withdraw from the study at any time. Measurements already made would still be used if you were to agree to this.

What will happen to samples taken in the study?

We will take samples of blood, urine and saliva during this study. Because we cannot analyse all of the samples straightaway, we will need to place some of the samples in storage. Samples will be taken, processed and then frozen and stored in a controlled-access freezer in the Clinical Research Facility. Each sample will be anonymised using a unique participant code and cannot be traced back to the individual. After samples have been fully analysed they will be destroyed.

What will happen to data from this study?

Personal data will be stored in medical notes created at the Clinical Research Study for use during the study. Only members of the research team will have access to this information and hard files will be stored in a secured filing cabinet behind controlled-access doors. Personal data will be anonymised by the Chief Investigator and thereafter only codes will be used to identify participant data. Clinical data will not be released to anyone other than the research team. All study data will be analysed at Newcastle University by members of the research team using statistical software. Dr Daniel West (Chief Investigator) will act as custodian for the data generated by the study. After the study has ended, files will be stored under password protection and in locked cabinets and archived appropriately.

Who is organising and funding the research?

This project is funded by Newcastle University as a PhD studentship. The design and organisation of the study is the responsibility of Tess Capper, Prof Emma Stevenson and Dr Mario Siervo, the latter of whom is recognised as an expert in this field.

Design of this information sheet

This document is written in accordance with the requirements of the European Clinical Trials Directive 2001/20/EC, the ICH Good Clinical Practice guidelines and the UK Medicines for Human Use (Clinical Trials) Regulation 2004.