VOLUNTEER INFORMATION SHEET

Propionate supplementation and blood vessel stiffness  
(PROPAC study)

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

Talk to others about the study if you wish.  
Part 1 tells you the purpose of this study and what will happen to you if you take
part.  
Part 2 gives you more detailed information about the conduct of the study.  
Please contact us if there is anything that is not clear.

Part 1

What is the purpose of the study?

We know that whole grain foods (oats, unrefined wheats etc.) can lower blood
pressure. Recent studies suggest that breakdown of indigestible fibres by gut
bacteria releases substances called short chain fatty acids, which cause this effect on
blood pressure. These substances, including one called propionate, are commonly
used as food additives, and are known to be safe. We want to find out if taking a
propionate-containing drink will help to reduce blood vessel stiffness.

Do I have to take part?

No, it is up to you to decide to join the study. The study is fully described in this
patient information sheet. You are free to withdraw at any time, without giving a
reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

If you agree to take part, you will be asked to attend the Human Nutrition Unit at the
Rowett Research Institute of Nutrition and Health. There will be an initial short visit
to so that we can answer any questions you may have, and you will be asked to sign
the consent form. You will also be given a food diary to complete and bring back at
your next appointment. You will then be given an appointment to come for the first
study visit. This will last about 3.5 hours, and breakfast will be provided. You will be
asked to refrain from eating any wholegrain foods, beans, pre- or probiotics as well
as foods high in dietary fibre for at least three days before the intervention. You will
receive a list of food items you may consume on this day as well as food items to
avoid. You will be asked to fill in a Health questionnaire. You will have a line inserted
in your arm for taking blood, and some blood (5ml or one teaspoonful) will be taken.
at baseline. Following this you will have a 24 hour blood pressure monitor fitted to the other arm. The stiffness of your blood vessels will also be measured. This is a simple and painless procedure, similar to blood pressure measurements. You will then be allocated to one of two different treatments: this will happen randomly (like tossing a coin). You will be given breakfast which includes a drink containing calcium propionate or a regular drink (not containing any propionate but otherwise the same). From the line in your arm, bloods (one teaspoon) will be taken after 15 min, 30 min, 1 hr and 3 hr after ingesting the drink. The stiffness of your blood vessels will also be measured at the same time points.

The line in your arm will be removed and you will then be able to go home, and come back the following morning for a further blood test and blood vessel stiffness measurement. The blood pressure monitor will also be removed. Your bloods will be tested to look at how long it takes for the propionate to appear in the blood, and your blood vessel stiffness and blood pressure will be looked at to see if there is any evidence of an effect of the drinks. At the end of the first visit, another appointment for the second and last visit will be given (2 to 4 weeks later), during which you will follow the same procedures. However, this time you will be given the drink you did not have the first time. This will help us to compare the effects of both drinks in the same person.

Up to ten pounds will be available to help with travel expenses. We will send you a copy of the results after the whole study is completed.

**What will I have to do?**

You will have to avoid whole grain foods at least three days before each study visit, and not have anything to eat from midnight before your visit. You will be given breakfast when you come to the Rowett.

**What are the side effects of any treatment received when taking part?**

Calcium propionate is commonly used as a preservative in bread, and is not associated with any side effects in the doses proposed, which will be similar to the amount produced by bacteria in the gut.

**What are the possible benefits of taking part?**

The study will not be of direct benefit to you. The main purpose is to improve knowledge of how whole grain foods might affect blood vessel stiffness, and perhaps contribute to the evidence base around blood pressure management.

**What happens after the study?**

Once the study has completed, all participants will be notified of the results by letter.
Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

*If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.*

**Part 2 of the information sheet**

What if relevant new information becomes available?

If any information becomes available which impacts on the study, we will let you know about this.

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

If you withdraw from the study, we will destroy all your identifiable samples if you wish, otherwise we will use the data collected up to your withdrawal. We will however keep your anonymised samples.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Dr F Thies, 01224 437954 or 438634, Dr Mary Joan Macleod 01224 550808].

In the event that something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against the University of Aberdeen but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?

All study data will be stored in password protected files, and any paperwork will be stored in a locked office under the care of Dr Thies. All collected information about you will be relevant to the study and treated according to University of Aberdeen guidelines. The study data will be stored for up to fifteen years, and disposed of securely. The only people having access to the data will be the study team and any personnel from the university who have a role in checking that the study is being carried out correctly.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will be informed that you have taken part in the study only if abnormal results are found.

What will happen to any samples I give?
The blood samples which you donate will be used to measure the levels of propionate in the blood as well as other chemicals involved in blood vessel function. If further analysis becomes necessary e.g. for hormones involved in blood pressure control, we will use the samples for this. With your consent, they will be stored according to local guidelines for human blood samples for future analysis and future research, subject to separate ethical approval.

**What will happen to the results of the research study?**

This study is to help decide whether dietary propionate could positively influence blood vessel stiffness. This information will be used for the follow on studies which will look at the effect on blood pressure. All data being stored for over 3 years will be in fully anonymised form.

**Who is organising and funding the research?**

The research is being organised through the Rowett Institute, University of Aberdeen, and is being funded by the Rural Environment Science and Analytical Services (RESAS) programme from Scottish Government.

**Who has reviewed the study?**

All research in the NHS and University is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the North of Scotland Research Ethics Service.

**Further information and contact details**

Further information about the study is available from Dr F Thies (f.thies@abdn.ac.uk), 01224 437954 or 438634, Dr MJ Macleod (m.j.macleod@abdn.ac.uk) 01224 437842. If you would like some independent advice about the study, you can obtain this from Dr Isobel Ford ([i.ford@abdn.ac.uk](mailto:i.ford@abdn.ac.uk)).