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Effects of wholegrain-derived compounds supplementation on blood vessel stiffness

Submission date	Recruitment status	[_] Prospectively registered
02/04/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/04/2021	Circulatory System	

Plain English summary of protocol

Background and study aims
Whole grain foods such as oats, unrefined wheat and rye have been shown to be effective at reducing blood pressure, especially in the elderly or those with high blood pressure (hypertension). Recent studies suggest that the breakdown of indigestible fibres contained in these products by gut bacteria releases substances called short chain fatty acids (SCFAs), which are able to lower blood pressure. These substances, including one called propionate, are commonly used as food additives, and are known to be safe. The aim of this study is to find out the effects of drinking a propionate-containing drink on blood vessel stiffness (the hardening of the arteries meaning that the heart has to work harder to pump blood around the body, raising blood pressure), and whether this translates to a beneficial effect on blood pressure.

Who can participate?
Healthy men aged 40 to 65

What does the study involve?
Participants attend two study visits spaced two to four weeks apart. For three days before attending the study visits, participants are asked not to eat any wholegrain foods, beans, pre- or probiotics. At the first study visit, participants are randomly allocated to receive one of two treatments. The first treatment involves drinking a 150ml drink containing 3mg calcium propionate, and the second treatment involves drinking a 150ml drink identical inconsistency that does not contain calcium propionate. At the start of each study visit, participants have a tube placed into a vein in their arm and have a blood sample taken, as well as having the stiffness of their blood vessels measured with a specialised device similar to having blood pressure measured. A 24 hour blood pressure monitor is also fitted so that blood pressure can be measured continuously over the next 24 hours. Participants then consume a breakfast containing the drink that have been allocated to for that study visit and have blood samples taken through the tube in their arm after 15 minutes, 30 minutes, 1 hour and 3 hours. Blood vessel stiffness is measured on the other arm at the same times. Participants then return the following morning for a final blood test and blood vessel stiffness measurement and the blood pressure monitor is also removed so the results can be reviewed.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with taking part in the study.

Where is the study run from?
Human Nutrition Unit at the Rowett Research Institute of Nutrition and Health, University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?
January 2013 to September 2017

Who is funding the study?
Scottish Government (UK)

Who is the main contact?
1. Miss Karolin Muzs (public)
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2. Dr Frank Thies (scientific)
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Study website
https://www.abdn.ac.uk/rowett/volunteer/propac-study-813.php

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of short chain fatty acid supplementation on vascular function in middle-aged volunteers

Acronym
PROPAC

Study objectives
Supplementation with calcium propionate modulates vascular function in healthy middle-aged individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland research ethics committee, 07/10/2015, ref: 15/NS/0099

Study design
Single-centre double-blind cross-over randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
https://www.abdn.ac.uk/rowett/documents/PROPAC_PIS.pdf

Health condition(s) or problem(s) studied
Blood pressure

Interventions
Participants receive the intervention and control treatment in a random order, which are delivered at separate study visits (2-4 weeks apart). Before the study visit, participants are 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. At baseline, participants have a 5ml sample of blood taken, a 24 hour blood pressure monitor fitted to their other arm and their blood vessel stiffness measured.

Intervention: Participants will be given breakfast which includes a 150ml drink containing 3g calcium propionate.
Control: Participants will be given breakfast which includes an identical 150ml drink which does not contain calcium propionate.

In each condition, blood samples are take 15 minutes, 30 minutes, 1 hour and 3 hours after ingesting the drink. Blood vessel stiffness is measured at the same timepoints. Participants return the following morning for another blood test and blood vessel stiffness measurement. The 24 hour blood pressure monitor is also removed at this point.

Intervention Type
Supplement

Primary outcome measure
Arterial function measured by pulse wave analysis

Secondary outcome measures
1. Blood pressure measured using the 24 hour blood pressure monitor over the 24 hours following each of the two study visits
2. Systemic markers of endothelial function
3. Blood pressure regulation

Overall study start date
01/06/2015

Completion date
01/09/2018

Eligibility

Key inclusion criteria
1. Male
2. Aged 40-65 years old
3. 115mmHg ≥ systolic blood pressure ≤159mmHg & 70mmHg ≥ diastolic blood pressure ≤ 99mmHg
4. BMI between 19 and 30 kg/m2

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
25

Key exclusion criteria
1. BMI under 19 kg/m2 or over 30kg/m2
2. Systolic blood pressure >159mmHg or <115mmHg & diastolic blood pressure
3. Any pharmalogical treatment for hypertension or depression
4. Suffering from eating disorders and/or taking any nutritional supplements, and/or usually eating high intake of wholegrains or probiotics

Date of first enrolment
14/01/2016

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Aberdeen
Human Nutrition Unit
Rowett Institute of Nutrition and Health
Foresterhill
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Sponsor information

Organisation
The University of Aberdeen

Sponsor details

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Sponsor type
University/education

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Scottish Government

Alternative Name(s)
The Scottish Government, Scottish Executive, Riaghaltas na h-Alba

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study protocol and statistical analysis will be available on request from 01/09/2018 onwards. Results are planned to be published in a high impact peer reviewed journal by June 2019 and may also be presented at a conference prior to publication.

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan

All the volunteers participating to the study gave consent. All data/samples from human volunteers are stored in accordance with the Human Tissue act. All human samples are also coded to ensure anonymity. Visit data consisting of hard-copy questionnaires (health and food intake), height, weight, and blood pressure and arterial stiffness measurements, as well as blood data are stored as paper copies in secured, locked room and cabinet and on secure computer spreadsheets. All data are anonymised and stored in a repository with restricted access. Data will be presented at conferences prior to publication in open access journals. Any published papers will be deposited in PURE to comply with internal open access requirements. Research outputs, including datasets, will be recorded on the institutional research information systems. All electronic data will be archived centrally on University backed up servers. Data will be made available on request after publication of the main outcomes.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Thesis results			23/04/2021	No	No
HRA research summary			28/06/2023	No	No