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The effects of a high oat diet on risk factors of heart disease and their link with gut health

Submission date	Recruitment status	[ ] Prospectively registered
25/05/2015	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
03/06/2015	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
15/10/2020	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cardiovascular disease (CVD), such as stroke or heart attack, is A major cause of death and Scotland has amongst the highest mortality (death) rates in Western Europe. Recent studies have shown that diets rich in wholegrain foods, such as oats, can help to reduce the risk of chronic diseases, such as CVD, as well as lower blood pressure. The way in which oats are digested and their effect on the gut may also provide health benefits. The reasons for this, however, are not yet fully understood.
The purpose of the study is to look at the effects of an oat-rich diet on indicators of heart health, such as cholesterol, blood pressure and other factors in the blood that are associated with CVD. We also want to look at the way in which oats affect different types of bacteria in the gut, which is important for learning how oats are digested.

Who can participate?
Healthy adults between the ages of 40-65.

What does the study involve?
The study involves 5 visits to the trial centre, 1 screening visit to check the participant is eligible, and 4 subsequent visits at weeks 1, 4, 10 and 16 of the dietary study period when samples and measurements will be taken. For weeks 1 to 4 participants are free to eat their normal diet but their intakes of wholegrain foods and oat-based foods is restricted (refined diet). From week 4 onwards they are randomly allocated to either continue on this refined diet or switch to an oat-rich diet for the rest of the study. Within each group, participants are asked to eat at least 100g per day of the relevant grains i.e. refined grains or oats, using commercially available products such as breakfast cereals and breads. At each of the visits, except the screening appointment, participants come in after a 12 hour fast and a small blood sample taken. They also have their weight, height, blood pressure and arterial stiffness measured. They are asked to collect all their urine for the 24-hours prior to each sample appointment and to give a faecal sample on the day of the appointment. To measure the participants' ambulatory blood pressure they are also asked to wear a portable blood pressure monitor for the 24 hours following the visits at weeks 4 and 16. Each participant's diet is assessed prior to and during the study by asking them to complete a 4-day food diary, a record of everything they eat and drink during this period, prior to each sampling appointment.

What are the possible benefits and risks of participating?
The information collected from the study may help to find ways of reducing other people's risk of developing diseases, such as CVD. Participants will receive a confidential report at the end of the study detailing their own weight, blood pressure, cholesterol and blood glucose levels during the study. There are no known side-effects of eating any of the foods used in the study but participants may experience slight discomfort when providing a blood sample.

Where is the study run from?
The study is being coordinated at the University of Aberdeen's Rowett Institute of Nutrition and Health, Aberdeen (UK)

When is the study starting and how long is it expected to run for?
August 2012 to September 2015

Who is funding the study?
The Scottish Government's Rural and Environment Science and Analytical Services Division (RESAS)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OGHH2011

Study information

Scientific Title
The effect of a high oat diet on cardiovascular disease risk and the association with gut microbiota in healthy, middle-aged people

Study objectives
100g per day of oats, incorporated into the habitual diet, will decrease blood pressure within healthy, middle-aged individuals. This decrease is linked to changes in the gut microbiota and their products which are taken back into circulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Aberdeen, Rowett Institute of Nutrition and Health Ethical Review Panel, 24/10/2012, ref: 12/HSMC/2008

Study design
Single-centre randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
The intervention group consume 100g of oats per day as part of their habitual diet. The control group consume 100g per day of refined cereal-based products i.e. no wholegrain foods, also as part of their habitual diet. Both groups are asked to do this for 12 weeks, following a 4-week run-in period where all participants follow the control group diet.

Intervention Type
Other

Primary outcome measure

1. Blood pressure is measured after a 10 minute recumbent rest period. A minimum of 3 readings are taken and the first one is discarded. 24-hour blood pressure monitors are also used for the 24-hour following each timepoint. Readings are taken every 30 minutes between 7am and 10pm and then every hour from 10pm to 7am
2. Faecal samples are collected at each timepoint and analysed for bacterial composition and short chain fatty acid concentrations

All primary outcomes are measured at the timepoints of weeks 0, 4, 10 and 16, with weeks 4 to 16 being the 12 week intervention period.

Secondary outcome measures
1. Fasted blood samples are analysed for blood lipid and glucose profiles and a range of inflammatory markers associated with cardiovascular disease, as well as short chain fatty concentrations
2. Urine samples are collected at weeks 4 and 16 and analysed for avenanthramide concentration as a marker of dietary compliance

Secondary outcomes are measured at the timepoints weeks 0, 4, 10 and 16, with weeks 4 to 16 being the 12 week intervention period.

Overall study start date
06/08/2012

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Males and females
2. Aged 40-65 years
3. BMI 18.5-30.0
4. Systolic blood pressure > 90 and < 160, diastolic blood pressure > 60 and <99. Blood pressure will be measured at the screening appointment, and if greater than 140 / 90 the volunteer will be referred to their GP before participation. If they are subsequently put onto blood pressure medication then they will be excluded from the study

Participant type(s)
Healthy volunteer

Age group
Other

Sex
Both

Target number of participants
60

Key exclusion criteria

1. History of CVD
2. History of diabetes or previously diagnosed impaired glucose tolerance (fasted glucose >7.0mmol/l and 2 hour glucose levels following a glucose load of ≥7.8 and <11.1 mmol/l)
3. Untreated thyroid disorders
4. Presence of rheumatoid arthritis
5. Presence of asthma
6. Presence of inflammatory bowel disease
7. Presence of autoimmune disorders
8. Presence of cancer
9. Taking any medication or supplements that are prone to affecting any outcome measures including medication for blood pressure and hypercholesterolaemia
10. Use of n3 fatty acid supplements
11. Taken a course of antibiotics within the last three months

Date of first enrolment
11/01/2013

Date of final enrolment
29/01/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Rowett Institute of Nutrition and Health, University of Aberdeen
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Sponsor information

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Funder(s)

Funder type
Government

Funder Name
The Scottish Government's Rural and Environment Science and Analytical Services Division (RESAS)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration