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Effect of regular mealtime inclusion of oat-based products on glycaemic response and post-prandial inflammation in type 2 diabetes

Submission date
10/02/2009

Recruitment status
No longer recruiting

Registration date
29/05/2009

Overall study status
Completed

Last Edited
02/02/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). In the UK, the first step in treating T2DM is by making lifestyle changes, such as eating a healthier diet and exercising more. Changes in diet, such as cutting out sugar or eating different types of sugars have been shown to be very effective at controling the symptoms of T2DM. However it is still unclear as to what the best diet for improving blood sugar (glycaemic control) is. Eating oats is considered to be avery effective way of improving glycaemic control, as they fill you up but do not raise blood sugar like other carbohydrates. The aim of this study is to find out whether a healthy diet rich in oats is more effective at improving glycaemic control than standard dietary advice given to type 2 diabetics.

Who can participate?
Men and post-menopausal women aged between 40 and 75 with T2DM managed by diet alone.

What does the study involve?
At the start of the study, all participants eat a standard meal and have their blood sugar measured so that their processing of glucose can be assessed. Participants are then randomly allocated to one of two groups. Participants in the first group are given standard dietary advice that is given to people with T2DM, which is based on the current healthy eating recommendations, as well as written information giving further diet and lifestyle advice, such as the importance of a low fat diet, low alcohol and no smoking. These participants are asked to avoid oats for the eight week period. Participants in the second group are given a range of selected commercially available oat-based products (including cereals, oatcakes, bread, cereal bars) to eat over the eight week diet. After eight weeks, participants repeat the standard meal test and then start the other diet for eight weeks (the healthy eating group now eat the oat-enriched diet and vice versa. At the end of the eight weeks, the standard meal test is repeated in order to find out which diet is better at helping patients to control their blood sugar.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
UHI Millennium Institute (UK)

When is the study starting and how long is it expected to run for?
February 2008 to December 2009

Who is funding the study?
1. NHS Highland Research and Development Department (UK)
2. Chief Scientist Office of the Scottish Executive Health Department (UK)

Who is the main contact?
Professor Sandra MacRury

Contact information

Type(s)
Scientific

Contact name
Prof Sandra MacRury

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effect of regular mealtime inclusion of oat-based products on glycaemic response and post-prandial inflammation in type 2 diabetes: a randomised cross-over study

Study objectives
A diet with regular inclusion of oat-based products will lead to improvements in post-prandial hyperglycaemia, post-prandial inflammation including platelet aggregation, glycaemic control, lipid profile and insulin resistance as measured by the homeostasis model assessment of insulin

resistance (HOMAIR) in individuals with type 2 diabetes when compared to standard dietary advice. Such improvements will be more effective than those in response to standard dietary advice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 11/01/2008, ref: 07/S0802/163

Study design
Randomised multicentre cross-over design study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dietary management of type 2 diabetes

Interventions
Participating individuals will follow a randomised cross-over protocol and will follow both conventional diet advice and a modified diet, based on oat products each for an 8-week period. Standard dietary advice is based on healthy eating principals and participants will all have been provided with dietary advice at time of diagnosis. In order to standardise this advice as much as possible we will provide all participants with standard literature (Diabetes UK "Eating well with Diabetes"). We will also ask them to limit their oat intake to 20 g/day on average. Whilst following the oat-based diet participants will be provided with oat products such as cereals, oat cakes, oat bread, cereal bars, etc., and will receive written advice as to how these can be included in the diet. Participants will be asked to substitute part or all of the carbohydrate at each meal with an oat product. They will be asked to record the amount of oat products consumed based on a 'points system' in a food diary that will be collected along with any uneaten oat products every 2 weeks. Together this information will be used to assess oat product consumption. The aim will be to include a minimum of 70 - 100 g of oats on a daily basis.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oat-based products

Primary outcome(s)
1. Diabetes control assessed by HbA1c using Diabetes Control and Complications Trial (DCCT) aligned laboratory equipment
2. Post-prandial glycaemia assessed by a 3-day period of continuous blood glucose monitoring at weeks 0, 8 and 12 (Medtronic Minimed device) and glycaemic response to a standard test meal

carried out at weeks 0, 8 and 16
3. Post-prandial inflammatory responses to a standard test meal carried out at weeks 0, 8 and 16 (C-reactive protein [CRP], tumour necrotising factor-alpha [TNF-alpha] and interleukin-6 [IL6] using bead array kits)
4. Measurements of platelet activation status by a combination of functional studies, measurement of surrogate markers such as P-selectin and platelet microparticles at weeks 0, 8 and 16
5. Insulin resistance measured at weeks 0, 8 and 16 by measurement of plasma insulin and glucose in the fasting state and calculation of HOMAIR and HOMAbeta-cell
6. Markers of oxidative stress in the fasting and post-prandial state at 0, 8 and 16 weeks will be assessed in the Free Radical Research Laboratory, Inverness by oxygen radical antioxidant capacity (ORAC), 4-hydroxynonenal/malondialdehyde (TBARS commercial assay kit; measure of lipid peroxidation) and urinary isoprostanes/creatinine ratio
7. Post-prandial insulin responses measured at 0, 8 and 16 weeks following a standard test meal

Key secondary outcome(s))
1. Plasma enterolactone will be measured as a marker of wholegrain consumption at 0, 8 and 16 weeks
2. Weight, body mass index (BMI), waist circumference, blood pressure and skinfold thickness measured at 0, 8 and 16 weeks
3. Standard questionnaires used routinely at the Rowett Institute of Nutrition and Health will be used to assess quality of life (using brief WHO-QOL questionnaire) exercise habits (using IPAQ questionnaire) and perception of diabetes (using the IPQ-R diabetes questionnaire) at 0, 8 and 16 weeks
4. Assessment of dietary intake will be undertaken at 0, 8 and 16 weeks using a weighed food diary
5. Assessment of hunger, satiety and palatability of the diet using hourly Visual Analogue Scale questionnaires at 0, 8 and 16 weeks

Completion date
20/12/2009

Eligibility

Key inclusion criteria
1. Men and post-menopausal women
2. Type 2 diabetes managed by diet alone
3. HbA1c not greater than 7.5%
4. Aged 40 - 75 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Significant liver, renal, cardiovascular or psychiatric illness
2. Medications that might invalidate the study results (including corticosteroids, hormone replacement therapy [HRT], anticoagulants, aspirin and statins)

Date of first enrolment
01/02/2008

Date of final enrolment
20/12/2009

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
UHI Millennium Institute
Inverness
United Kingdom
IV2 3JH

Sponsor information

Organisation
University of Highlands and Islands (UK)

ROR
https://ror.org/02s08xt61

Funder(s)

Funder type
Government

Funder Name
NHS Highland Research and Development Department (UK) - initial funding

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK) - full grant awarded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes