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Exploring targeted nutritional interventions to prevent diabetes

Submission date
27/02/2017

Recruitment status
No longer recruiting

Registration date
07/03/2017

Overall study status
Completed

Last Edited
11/08/2023

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). Pre-diabetes is a condition where a person's blood sugar levels are higher than normal, but nor high enough to be classified as T2DM. If left untreated, then pre-diabetes can turn into T2DM. Impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) are both subtypes of pre-diabetes and carry the same risk of developing into diabetes. However, weight loss and exercise, which reduce the risk of diabetes in people with IGT, do not appear to be effective in people with IFG. Since about a third of people with pre-diabetes have IFG, this could mean there is currently no known method of preventing diabetes in a large number of people. Consumption of a simple dietary fermentable carbohydate called inulin has been shown to reduce fasting insulin resistance, and also increase early insulin secretion (release). Since people with IFG have impaired insulin secretion and fasting insulin resistance, inulin may be a targeted, effective method to prevent diabetes in people with IFG. The aim of this study is to look at the effect of inulin on blood sugar.

Who can participate?
Adults with IFG or IGT.

What does the study involve?
This study compares three groups of participants, all of whom consuming a low-calorie-diet for sixweeks in order to lose 5-7% of their body weight. Those in the first group have IFG, those in the second group have IGT and those in the third group are people with IFG who are also asked to take inulin supplements throughout the study. At the start of the study, all participants undergo a series of tests to see how well their bodies process glucose (sugar) and how well their bodies respond to/produce insulin. After six weeks of the diet (and inulin supplementation for those in the third group), participants attend a study visits where these tests are repeated.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating, however should the study discover something about a participant's health then they are informed so that they can seek treatment.

Some of the procedures in this study, such as the recording of a person's weight, height and blood pressure present no risk. Other procedures, such as taking blood samples, can cause mild discomfort. The risks of taking a blood sample include: slight discomfort when the needle is inserted and possible bruising and a localised infection. These procedures will only be carried out by experienced staff under aseptic conditions to minimise all these risks. There are some side-effects of weight loss which are mild and may include fatigue, feeling cold, bad breath or hair falling out. However, these are only short-term and should disappear within a few days or at the end of the diet. There are some side-effects of introducing a fibre (inulin) into the diet, but these should be mild and disappear in a few days. The dose of inulin will be increased slowly which should minimise these effects.

Where is the study run from?
NIHR/Wellcome Trust Imperial Clinical Research Facility, Hammersmith Hospital (UK)

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

Who is funding the study?
Diabetes UK (UK)

Who is the main contact?
Ms Nicola Guess
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
19648

Study information

Scientific Title

Effect of weight loss on blood glucose control in subjects with Impaired Fasting Glucose versus Impaired Glucose and the effect of inulin on blood glucose control in subjects with Impaired Fasting Glucose only

Study objectives
The aim of this study is to evaluate the effects of a very low calorie diet in patients with impaired fasting glucose (IFG) and patients with impaired glucose tolerance (IGT) and daily inulin supplements in patients with IFG only.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South East Coast - Surrey, 01/07/2015, ref: 15/LO/0989

Study design
Non-randomised; Interventional; Design type: Prevention, Not Specified

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Diabetes, Primary sub-specialty: Other

Interventions
All participants attend a health screening which includes an oral glucose tolerance test. The health screening should last about 2.5 hours. All participants will attend a 2.5 hour baseline study day to assess blood glucose levels before the very low calorie diet or inulin supplementation. The weight loss and inulin supplementation both last for 6 weeks. Following the very low calorie diet or inulin supplementation participants return for a follow-up study day. The baseline and follow-up study days will last about 2.5 hours and enable the measurement of blood glucose and insulin levels. Participants in the weight loss group only will attend weekly weigh-ins during the 6-week diet. All participants will receive dietary advice after they finish the study to help them prevent type 2 diabetes long-term.

Intervention Type
Other

Primary outcome(s)
Fasting blood glucose is measured using a venous blood sample taken following a 10-hour fast at baseline and 6 weeks.

Key secondary outcome(s))
1. HOMA-IR is measured using fasting glucose and insulin samples from: https://www.dtu.ox.ac.uk/homacalculator/ at baseline and 6 weeks
2. Fasting insulin is measured using a venous blood sample taken following a 10-hour fast at baseline and 6 weeks

3. Insulin secretion as measured by Insulin Secretion Index (ISI) calculated as the ratio of total AUC insulin to total AUC glucose taken from the meal tolerance test, with blood samples collected at 5, 15, 20, 30, 60, 90 and 120 minutes at baseline and 6 weeks
4. tAUC glucose calculated using the trapezoid measure taken from venous glucose samples collected at 0, 5, 15, 20, 30, 60, 90 and 120 minutes at baseline and 6 weeks
5. tAUC insulin calculated using the trapezoid measure taken from venous insulin samples collected at 0, 5, 15, 20, 30, 60, 90 and 120 minutes at baseline and 6 weeks
6. Body weight measured to one decimal point in light clothes and shoes removed at baseline and 6 weeks

Completion date
29/11/2017

Eligibility

Key inclusion criteria
1. Adults over 18 years of age
2. Isolated- impaired fasting glucose (fasting plasma glucose of 6.1-6.9mmol/L and 2 hour plasma glucose following 75g glucose of < 7.8mmol/L) or isolated -impaired glucose tolerance (fasting plasma glucose of <6.1 mmol/L and 2 hour plasma glucose following 75g glucose of >7.8mmol/L < 11.1 mmol/L)
3. BMI between 25--35 kg/m2
4. The volunteers should have given full written consent.
5. Have had a stable body weight for the last 3 months (< 5% change)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnant and lactating women
2. Volunteers unable to give informed consent for themselves
3. Volunteers with a major metabolic disease – including diabetes
4. Has a known/diagnosed gastrointestinal problems inflammatory bowel disease, irritable bowel syndrome etc.
5. Failure of the medical examination for inclusion into the study
6. Those with anaemia (Hb <10g/l)

7. Drug or alcohol abuse in the last 2 years
8. Regular ingestion of specifically labelled prebiotic or probiotic functional foods for two weeks before commencement of the study and then for the duration of the intervention

Date of first enrolment
12/02/2016

Date of final enrolment
29/09/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Hospital
NIHR/Wellcome Trust Imperial Clinical Research Facility,
Du Cane Road
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College London and Imperial College Healthcare NHS Trust

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)

The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/11/2015	11/08/2023	Yes	No
HRA research summary			26/07/2023	No	No