

Effect of change in pancreas and liver fat content upon beta cell function and hepatic insulin action during weight loss in type 2 diabetes

Submission date

23/04/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/04/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

22/02/2019

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

6722

Study information

Scientific Title

Effect of change in pancreas and liver fat content upon beta cell function and hepatic insulin action during weight loss in type 2 diabetes: a non-randomised interventional treatment trial

Acronym

DRN 328 Pancreatic Fat Study

Study objectives

The aim of this study is to determine the metabolic effects of decreasing excess fat in the liver and pancreas in patients with type 2 diabetes. During an 8-week hypocaloric diet, the study will define the time course of change in response to glucose-induced insulin secretion in relation to change in pancreatic fat content and will define the time course of change in liver insulin sensitivity in relation to change in liver fat content.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle upon Tyne and North Tyneside 2 Ethics Committee, 15/06/2009, ref: 09/H0907

Study design

Non-randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network, Primary Care Research Network for England; Subtopic: Both, Not Assigned; Disease: Diabetic Control, Metabolic, Obesity

Interventions

The study involves an 8-week period of very low calorie diet (800 cal per day) using liquid based-formula diet (Optifast®) to induce weight loss. In addition to the three sachets of Optifast® per day, participants are asked to eat 240 g of non-starchy vegetables per day and drink at least 2

litres of water or calorie-free beverages per day. During the intervention period, participants are monitored on weekly to fortnightly basis by members of the research team which includes a specialist dietician.

Follow Up Length: 3 months

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Liver fat content
2. Pancreatic fat content
3. Hepatic insulin sensitivity
4. Glucose-induced insulin secretion

Each of the above is measured at baseline, week 1, week 4 and week 8.

Secondary outcome measures

Glucose control

Overall study start date

01/10/2009

Completion date

01/05/2011

Eligibility

Key inclusion criteria

For type 2 diabetes volunteers:

1. Duration of diabetes up to 2 years
2. Aged between 25 - 65 years, either sex
3. Body mass index (BMI) of 30 - 40 kg/m² with stable body weight for preceeding 3 months
4. HbA1c between 6.2 and 9.0%
5. On treatment with diet alone or diet plus metformin

For healthy controls:

1. Normal glucose tolerance plasma fasting triglyceride less than 1.8 mmol/l
2. No family history of type 2 diabetes
3. Matching BMI and age

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 22; UK Sample Size: 22

Key exclusion criteria

1. Kidney dysfunction (serum creatinine greater than 150 micromol/l)
2. Liver dysfunction (serum alanine aminotransferase [ALT] greater than 2.5 upper limit normal)
3. Contraindications to magnetic resonance imaging (MRI) (metal implants and claustrophobia)
4. Consumption of greater than 14 units of alcohol per week
5. Treatment with sulphonylureas, thiazolidinediones, steroids or beta-blockers

Date of first enrolment

01/10/2009

Date of final enrolment

01/05/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Musculoskeletal Research Group

Newcastle Upon Tyne

United Kingdom

NE2 4HH

Sponsor information**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details

Northern Centre for Cancer Care

Freeman Road

High Heaton

Newcastle upon Tyne

England

United Kingdom

NE7 7DN

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK (UK)

Alternative Name(s)

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	01/10/2011		Yes	No

