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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/04/2010	**Overall study status** Completed	
Last Edited 22/02/2019	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 fornightly 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/m^2 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