# Evaluation of pancreas composition and function during return to normal glucose tolerance in type 2 diabetes

Submission date Recruitment status Prospectively registered 21/06/2011 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 21/06/2011 Completed [X] Results [ ] Individual participant data Last Edited Condition category Nutritional, Metabolic, Endocrine 21/06/2016

# Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

Dr Sarah Steven

#### Contact details

Institute for Ageing and Health Campus for Ageing and Vitality Newcastle upon Tyne United Kingdom NE4 5PL

# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

10274

# Study information

#### Scientific Title

Evaluation of pancreas composition and function during return to normal glucose tolerance in type 2 diabetes

#### Acronym

**DRN 591** 

#### **Study objectives**

The overall objective is to elucidate the pathophysiology of type 2 diabetes by defining the contribution of change in beta cell function and insulin sensitivity to the return to normal glucose homeostasis during definitive therapeutic intervention. The compelling in vitro and in vivo animal data for a direct adverse effect of fatty acid exposure on beta cell function and hepatic insulin sensitivity will be tested in vivo in people with type 2 diabetes by use of a newly devised magnetic resonance technique. The specific hypothesis will be tested that the early effect of bariatric surgery in normalising blood glucose in type 2 diabetes is brought about by the same mechanistic changes as seen during hypocaloric dieting.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

10/H0906/78

#### Study design

Randomised interventional and observational treatment case-controlled study

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

#### Health condition(s) or problem(s) studied

Topic: Diabetes Research Network, Metabolic and Endocrine; Subtopic: Type 2, Metabolic and Endocrine (all Subtopics); Disease: Metabolic

#### **Interventions**

- 1. Subjects with and without type 2 diabetes will be investigated before and after gastric bypass surgery
- 2. Very low calorie diet (VLCD)
- 3. Subjects with T2DM will be randomised into 'surgery only' or 'VLCD+surgery' groups

#### Intervention Type

Mixed

#### Primary outcome measure

First phase insulin response at baseline, 1 week after intervention and 8 weeks after surgery

#### Secondary outcome measures

- 1. Liver fat and hepatic insulin sensitivity at baseline, 1 week after intervention and 8 weeks after surgery
- 2. The treatment induced changes in pancreatic fat content at baseline, 1 week after intervention and 8 weeks after surgery

#### Overall study start date

01/02/2011

#### Completion date

01/08/2012

# **Eligibility**

#### Key inclusion criteria

- 1. Type 2 diabetes duration less than 15 years
- 2. On treatment with diet alone or diet plus oral agents
- 3. BMI 35-45m/kg2
- 4. Listed for gastric bypass surgery
- 5. HbA1c < 10%

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

#### Target number of participants

Planned Sample Size: 28; UK Sample Size: 28

#### Key exclusion criteria

- 1. Waist circumference >150cm
- 2. Kidney dysfunction (serum creatinine >150 µmol/l)
- 3. Liver dysfunction (serum ALT > 2.5 times the upper limit of normal)
- 4. Contraindications to MRI (metal implants and claustrophobia)

- 5. Alcohol consumption >14 units per week
- 6. Treatment with thiazolidinediones, insulin, GLP1 analogues or steroids
- 7. History of bowel surgery or inflammatory bowel disease

#### Date of first enrolment

01/02/2011

#### Date of final enrolment

01/08/2012

# Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre Institute for Ageing and Health

Newcastle upon Tyne United Kingdom NE4 5PL

# Sponsor information

#### Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

#### Sponsor details

Claremont Wing Royal Victoria Infirmary Queen Victoria Road Newcastle Upon Tyne England United Kingdom NE1 4LP

#### Sponsor type

Hospital/treatment centre

#### Website

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

#### **ROR**

https://ror.org/05p40t847

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

European Foundation for the Study of Diabetes (Germany)

#### Alternative Name(s)

The European Association for the Study of Diabetes, EFSD

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

Germany

## **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	01/01/2016		Yes	No