

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

**Submission date**

21/06/2011

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

21/06/2011

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

21/06/2016

**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**

Dr Sarah Steven

**Contact details**

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

## Additional identifiers

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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/kg<sup>2</sup>
4. Listed for gastric bypass surgery
5. HbA1c < 10%

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### 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

United Kingdom

England

### 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

### 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, European Association for the Study of Diabetes (EASD), EFSD

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Germany

## Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

### Study outputs

Output type	Details results	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Results article</a>		01/01/2016		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes