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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
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/06/2016	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
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