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The effect of Roux-en-Y bariatric surgery on early and late cardiovascular risk markers in patients with obesity

Submission date
27/04/2009

Recruitment status
No longer recruiting

Registration date
13/05/2009

Overall study status
Completed

Last Edited
17/12/2014

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
R0782

Study information

Scientific Title
The effect of Roux-en-Y bariatric surgery on early and late cardiovascular risk markers in patients with obesity: an observational prospective study

Acronym
Bariatric surgery - CVR

Study objectives
To demonstrate the effects of Roux-en-Y bariatric surgery on both early and late manifestations of cardiovascular disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Riding Local Research Ethics Committee, approved on 12/03/2009 (ref: 09/H1304 /3).

Study design
Observational prospective longitudinal study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
Patients will be seen before surgery and then at 3 monthly intervals for 12 months after surgery. At each visit fasting bloods will be taken to determine insulin resistance along with fibrin structure and function. Endothelial function will be examined using Endo-PAT2000®.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To show that Roux-en-Y surgery significantly improves endothelial function.

Key secondary outcome(s))
To illustrate that bariatric surgery improves fibrin clot structure and function.

Completion date
30/09/2010

Eligibility

Key inclusion criteria

1. Both males and females, over age of 16 years
2. Body Mass Index greater than 40 kg/m^2, or greater than 35 kg/m^2 with comorbidity
3. To have Roux-en-Y bariatric surgery
4. Able to give informed consent
5. Consent to inform their GP's regarding their participation in the study
6. No changes to medication in last 3 months
7. Smokers can be included

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients not wishing disclosure to their GP's.

Date of first enrolment
14/04/2009

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
HS Brocklehurst Building
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
University/education

Funder Name
Diabetes Endowment Fund, University of Hull (UK)

Results and Publications

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	01/03/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes