

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	<input type="checkbox"/> Prospectively registered
Registration date 13/05/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/12/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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/m², or greater than 35 kg/m² 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