

# 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

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Other

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

To show that Roux-en-Y surgery significantly improves endothelial function.

**Secondary outcome measures**

To illustrate that bariatric surgery improves fibrin clot structure and function.

**Overall study start date**

14/04/2009

**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<sup>2</sup>, or greater than 35 kg/m<sup>2</sup> 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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40

**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**

England

United Kingdom

**Study participating centre**

**HS Brocklehurst Building**

Hull

United Kingdom

HU3 2RW

## **Sponsor information**

**Organisation**

Hull and East Yorkshire Hospitals NHS Trust (UK)

**Sponsor details**

Daisy Building

Castle Hill Hospital

Cottingham

England

United Kingdom

HU16 5JQ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hey.nhs.uk>

**ROR**

<https://ror.org/01b11x021>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Diabetes Endowment Fund, University of Hull (UK)

# 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?
<a href="#">Results article</a>	results	01/03/2014		Yes	No