Double-blind randomised controlled study to compare the outcomes of laparoscopic gastric banding and laparoscopic Roux-en-Y gastric bypass in morbidly obese patients attending the Multidisciplinary Morbid Obesity Clinic at King's College Hospital

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
30/04/2018	Nutritional, Metabolic, Endocrine	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr A G Patel

Contact details

Department of Surgery King's College Hospital Denmark Hill London United Kingdom SE5 9RS +44 (0)20 7346 3065 ameet.patel@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0116140810

Study information

Scientific Title

Double-blind randomised controlled study to compare the outcomes of laparoscopic gastric banding and laparoscopic Roux-en-Y gastric bypass in morbidly obese patients attending the Multidisciplinary Morbid Obesity Clinic at King's College Hospital

Study objectives

1. To compare the early outcome (first six months post-operatively) of the two operations with that of a matched group of morbidly obese patients who are on a low calorie diet only (controls)

2. To determine if there is any clinical and statistical difference in the outcomes of the two surgical procedures in the early, medium and long term (up to 5 years post-operatively)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Double-blind randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Obesity

Interventions

T compare the outcomes of laparoscopic gastric banding and laparoscopic Roux-en-Y gastric bypass

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2003

Completion date

01/09/2009

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2003

Date of final enrolment

01/09/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Department of Surgery London United Kingdom SE5 9RS

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Kings College Hospital NHS Trust R&D Consortium (UK)

Funder Name

NHS R&D support funding

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration