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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
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
30/04/2018

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

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

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date

01/09/2009

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration