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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

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
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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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 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