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Gastric bypass, adjustable gastric banding or sleeve gastrectomy surgery to treat severe and complex obesity

Submission date
01/09/2011

Recruitment status
No longer recruiting

Registration date
05/09/2011

Overall study status
Completed

Last Edited
04/04/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Obesity is an increasing health problem in the UK and is predicted to get worse. The three recognised operations in bariatric surgery are laparoscopic adjustable gastric banding (small inner tube placed around the stomach to reduce its capacity), laparoscopic gastric bypass (operation to make the stomach smaller and the digestive system shorter) and sleeve gastrectomy (operation to make the stomach smaller). This study aims to compare these three types of operation to see which one is better.

Who can participate?
The By-Band-Sleeve study is in follow up and is no longer recruiting new participants (added 24 /08/2022). Obese males and females over the age of 18 years who are referred for obesity surgery (at the recruiting centres) under current government guidelines can participate in the study. Participants should have a body mass index (BMI) of 40kg/m2 or more, or a BMI of 35 kg /m2 to 40 kg/m2 with other risk factors (e.g. type 2 diabetes), that could improve with weight loss.

What does the study involve?
Participants are randomly allocated to be treated with either gastric band surgery, gastric bypass surgery or sleeve gastrectomy surgery. Participants are also asked to complete a series of questionnaires at regular intervals up to three years after the operation about their quality of life, and some participants are invited to be interviewed about their experiences of treatment decisions. Researchers also ask participants to provide two blood samples in addition to the samples they would give as part of their normal care for future research into obesity.

What are the possible benefits and risks of participating?
There is no direct benefit for people enrolling in the study, although some people find that interviews help them talk through their situation and this is comforting. There should be no additional physical risk to you because all three operations offered are standard treatments for severe and complex obesity.

Where is the study run from?
University of Bristol (UK).

When is the study starting and how long is it expected to run for?
January 2012 to September 2022

Who is funding the study?
The National Institute of Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
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Study website
www.by-band-sleeve.bristol.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02841527

Secondary identifying numbers
HTA 09/127/53, 1279

Study information

Scientific Title

Gastric bypass, adjustable gastric banding or sleeve gastrectomy surgery to treat severe and complex obesity: a multi-centre randomised controlled trial

Acronym

By-Band-Sleeve

Study objectives

Current hypothesis as of 23/09/2015:
The By-Band-Sleeve study will compare the effectiveness, cost-effectiveness and acceptability of Band versus Bypass versus Sleeve surgery for treatment of severe and complex obesity.
We will test the following joint hypotheses:
1. Bypass is non-inferior to Band with respect to excess weight loss of more than 50% at three years and that Bypass is superior to Band with respect to HRQOL at three years
2. Sleeve is non-inferior to Band with respect to excess weight loss of more than 50% at three years and that Sleeve is superior to Band with respect to HRQOL at three years
3. Sleeve is non-inferior to Bypass with respect to excess weight loss of more than 50% at three years and that Sleeve is superior to Bypass with respect to HRQOL at three years

In the primary analysis both outcomes will be considered collectively, i.e. both hypotheses must be supported to conclude that Bypass is more effective than Band, or that Sleeve is more effective than Band or Sleeve is more effective than Bypass.

Specific objectives are to estimate:
1. The difference between groups in the proportion of patients achieving >50% excess weight loss at three years
2. The difference between groups in their average EQ-5D-5L health state score at three years
3. The difference between groups with respect to a range of secondary outcomes including generic, disease specific and gastro-intestinal symptom specific measures of HRQOL, adverse events, and resolution of co-morbidities; to explore, in a sub-sample, patients' experiences of management, outcome and eating behaviour change
4. The cost effectiveness of Band, Bypass and Sleeve

Previous hypothesis:
The joint hypotheses is that gastric BYpass is non-inferior to gastric BAND with respect to excess weight loss of more than 50% at three years and that BYpass is superior to BAND with respect to quality of life at three years. In the primary analysis both outcomes will be considered collectively, i.e. both hypotheses must be supported to conclude that BYPASS is more effective than BAND.

Specific objectives are to estimate:
1. The difference between groups in the proportion of patients achieving >50% excess weight loss at three years
2. The difference between groups in their average EQ-5D health state score at three years
3. The difference between groups with respect to a range of secondary outcomes including generic, disease specific and gastro-intestinal symptom specific measures of HRQOL, adverse events, and resolution of co-morbidities; to explore, in a sub-sample, patients' experiences of management, outcome and eating behaviour change.
4. The cost effectiveness of BAND and BYPASS

Ethics approval required

Old ethics approval format

Ethics approval(s)
South West Frenchay Research Ethics Committee, 14/10/2011

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Obesity

Interventions
Current interventions as of 23/09/2015:
All three surgical procedures (Band, Bypass and Sleeve) will be carried out laparoscopically. The methods used to create a pneumoperitoneum, the placement of the laparoscopic ports, and retractors are at the discretion of the surgeon. The type of instruments used is also at the surgeon's discretion. Undertaking a hiatal hernia (<5cm) repair and cholecystectomy are permitted but not compulsory. An apronectomy is prohibited at the time of surgery. Placement of drains is optional.

1. Laparoscopic adjustable gastric banding (Band surgery)
The type and size of adjustable gastric band is at the discretion of the surgeon. It is mandatory to i) dissect the lesser curve using the 'Pars flaccida' technique, ii) use non-absorbable gastro-gastric tunnelling sutures and iii) to fix the adjustable port to the anterior abdominal wall.

2. Laparoscopic gastric bypass surgery (Bypass surgery)
Methods used to create the biliary and gastric limbs are flexible, although upper limits of 75 cm and 150 cm are recommended for the biliary and gastric limbs, respectively. Routing of the Roux limb (antecolic or retrocolic) is flexible. The pouch can be created according to the surgeon's usual practice, except that a horizontal gastric pouch that includes fundus is prohibited. Use of a bougie is optional. Anastomoses can be performed as the surgeon chooses (e.g. stapled or sutured, single or double layer). Testing integrity of the anastomoses, and the closure of the mesenteric defects, is optional.

3. Laparoscopic sleeve gastrectomy surgery (Sleeve surgery)
It is mandated to visualise the left crus after dissection of the fundus. The type of bougie used is flexible although should be between 32 and 40 Fr. The type of stapler used is flexible and the use of additional sutures, clips, reinforcement of the staple line is at the discretion of the surgeon. Testing the integrity of the staple line is optional.

4. Concomitant interventions
Procedures will be carried out under general anaesthesia. All patients will receive peri-operative antibiotics and thromboprophylaxis in accordance with local policy. The use of nasogastric tubes, central and arterial lines, and urinary catheters is optional. After surgery, oral intake will be commenced according to local policy. The day of discharge will be chosen at the surgeon's discretion. The use of post-operative contrast swallows is optional.

Previous interventions:
Both BYPASS and BAND surgical procedures will be carried out laparoscopically in a standard fashion under general anaesthesia with all patients receiving antibiotic and DVT prophylaxis. For the purposes of this pragmatic trial each intervention will be allowed to be implemented according to the standard local policy. Particular aspects of each intervention that are considered mandatory or prohibited are listed below. Fidelity to the surgical interventions will be monitored by completion of an operative manual.

1. Laparoscopic adjustable gastric banding (BAND surgery)
The procedure will involve placement of laparoscopic ports, creation of a pneumoperitoneum and placement of retractors as the surgeon chooses. The choice about the type and size of adjustable gastric band will be made by the surgeon. If a hiatal defect is present it may be repaired and closure of pre-existing umbilical hernia or undertaking concomitant cholecystectomy is at the discretion of the surgeon. It is considered mandatory to dissect the lesser curve using the 'Pars flaccida' technique, to use gastro-gastric tunnelling sutures and to fix the adjustable port to the anterior abdominal wall. An apronectomy is prohibited.

2. Laparoscopic gastric bypass surgery (BYPASS surgery)
The laparoscopic ports, creation of a pneumoperitoneum and placement of retractors may be performed as the surgeon chooses. Creation of the biliary and gastric limbs and formation of the gastric pouch is performed as the surgeon chooses. An upper limit of 100cm and 200cm is recommended for the biliary and gastric limbs. Testing integrity of the anastomoses, closure of pre-existing umbilical, internal hernia and hiatal hernia defects are optional, as is undertaking a cholecystectomy. Formation of a horizontal gastric pouch that includes fundus and undertaking an apronectomy is prohibited.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 23/09/2015:
There are two primary endpoints:
1. The proportion achieving loss of greater than 50% of excess weight at three years (calculated as 100×[BMI at 3 years – BMI at randomisation*] / [BMI at randomisation – 25])
2. HRQOL at three years (EQ-5D-5Lhealth state score)
*Calculated using the participant weight recorded at baseline, after consent and before randomisation

Previous primary outcome measures:
The BY-BAND trial will compare weight loss and quality of life after the laparoscopic adjustable gastric banding operation (BAND) and the laparoscopic gastric bypass operation (BYPASS) to treat morbid obesity.

There are two co-primary outcomes:
1. The proportion achieving loss of greater than 50% of excess weight at three years (calculated as 100×[BMI at 3 years - BMI at randomisation] / [BMI at randomisation - 25])
2. HRQOL at three years (EQ-5D health state score).

The hypothesis that the trial is testing, that the Bypass operation is superior to the Band operation, will be supported if:
1. Bypass is not inferior with respect to weight loss at 3 year AND
2. Bypass is superior to Band with respect to health-related quality of life

Secondary outcome measures

Current primary outcome measures as of 23/09/2015:
To compare the cost effectiveness of the three operations, their acceptability and quality of life after surgery, nutritional outcomes, time to resolution of co-morbidities and complications. We will explore, in a sample, patients' experiences of surgery, outcomes and lifestyle change. We will also develop a core set of outcomes to use in future trials of morbid obesity surgery.

The secondary endpoints include:
1. Change in BMI over time adjusted for BMI at randomisation
2. % weight loss at 3 years
3. Waist circumference at 3 years
4. Time taken from randomisation to reach first loss of at least 50% of excess BMI
5. Time taken from first losing 50% excess BMI to first relapse (defined as weight re-gain such that the target of at least 50% of excess weight loss is no longer met)
6. Generic and symptom specific (i.e. obesity and GI specific) HRQOL: SF12, EQ5D, IWQOL-Lite, and GIQLI to three years
7. Resource use to three years
8. Standard NHS nutritional blood tests will be performed at each assessment including; full blood count, electrolytes, creatinine, glucose, HbA1c, liver function tests, iron, ferritin, vitamin B12, folate/red cell folate, lipid profile, 25-hydroxyvitamin D, calcium, parathyroid hormone
9. Measures of 24 hour recall eating using a standardised and validated interview process
10. Binge eating behaviour using a validated questionnaire
11. Adverse health events including the need for re-operation and cross over between interventions
12. Resolution of co-morbidities at 3 years, including sleep apnoea, non-alcoholic fatty liver disease, type 2 diabetes, hypertension and hyperlipidaemia
13. Time to resolution of sleep apnoea, type 2 diabetes, hypertension and hyperlipidaemia

Previous primary outcome measures:
To compare the cost-effectiveness of the two operations, their acceptability and quality of life after surgery, nutritional outcomes, time to resolution of co-morbidities and complications. We will explore, in a sample, patients' experiences of surgery, outcomes and lifestyle change. We will also develop a core set of outcomes to use in future trials of morbid obesity surgery.

1. Change in BMI over time adjusted for BMI at randomisation
2. Percentage weight loss at 3 years
3. Waist circumference at 3 years

4. Time taken from randomisation to reach first loss of at least 50% of excess BMI
5. Time taken from first losing 50% excess BMI to first relapse (defined as weight re-gain such that the target of at least 50% of excess weight loss is no longer met),
6. Generic and symptom specific (i.e. obesity and GI specific) HRQOL: SF12, EQ5D, IWQOL-Lite, and GIQLI to three years
7. Resource use to three years,
8. Standard NHS nutritional blood tests will be performed at each assessment including; full blood count, electrolytes, creatinine, fasting glucose, HbA1c, liver function tests, iron, ferritin, vitamin B12, folate/red cell folate, lipid profile, 25-hydroxyvitamin D, calcium, parathyroid hormone.
9. Measures of 24 hour recall eating using a standardised and validated interview process
10. Binge eating behaviour using a validated questionnaire
11. Adverse health events including the need for re-operation and cross over between interventions,
12. Resolution of co-morbidities at 3 years including sleep apnoea, non alcoholic fatty liver disease, type-2 diabetes, hypertension and hyperlipidaemia
13. Time to resolution of co-morbidities listed in 12 above

Overall study start date
01/01/2012

Completion date
30/09/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/09/2015:
Participants may enter study if ALL of the following apply:
1. Male or female patients
2. Over 18 years of age
3. Referred for bariatric surgery according to NICE guidelines - BMI of 40kg/m2 or more, OR BMI of 35 kg/m2 to 40 kg/m2 and other significant disease (e.g. type 2 diabetes or high blood pressure) OR BMI of 30 kg/m2 or more and recent onset diabetes OR Asian family origin with lower BMI and recent onset diabetes, that could improve with weight loss
4. Has been or is willing to receive intensive management in a specialist tier 3 obesity service
5. Fit for anaesthesia and surgery
6. Committed to follow-up and able to complete quality of life questionnaires
7. Able to provide written informed consent

Previous inclusion criteria:
The participant may enter study if ALL of the following apply:
1. Male or female patients
2. Over 18 years of age
3. Referred for bariatric surgery according to NICE guidelines - BMI of 40kg/m2 or more, OR BMI of 35 kg/m2 to 40 kg/m2 and other co-morbidities (e.g. type 2 diabetes), that could improve with weight loss
4. Willing to receive intensive management in a specialist obesity service
5. Fit for anaesthesia and surgery
6. Committed to follow-up and able to complete quality of life questionnaires
7. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1341

Total final enrolment
1351

Key exclusion criteria
Current exclusion criteria as of 23/09/2015:
Participants may not enter study if ANY of the following apply (assessed by patient history and clinical examination)
1. Previous gastric surgery or surgery for severe and complex obesity
2. Previous abdominal surgery or gastro-intestinal (GI) condition that precludes one or more of Band, Bypass or Sleeve
3. Large abdominal ventral hernia
4. Pregnancy (women who have given birth and women planning pregnancy will NOT be excluded)
5. Crohn’s disease
6. Liver cirrhosis and portal hypertension
7. Systemic lupus erythematosis
8. Known silicone allergy
9. Hiatus hernia >5cm
10. Other clinical/psychological reason, to be specified
11. Active participation in another interventional research study which might interfere with By-Band-Sleeve

Previous exclusion criteria:
The participant may not enter study if ANY of the following apply:
1. A history of previous gastric surgery or surgery for morbid obesity
2. Large abdominal ventral hernia
3. Hiatus hernia more than 5 cm
4. Pregnancy (women who have given birth and women planning pregnancy will NOT be excluded)
5. Crohn's disease
6. Liver cirrhosis and portal hypertension
7. Systemic lupus erythematosis
8. Known silicone allergy
9. Surgeon unwilling to for patient to be randomised (reason to be specified)

Date of first enrolment
01/11/2012

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
University Hospital Southampton
Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal Bournemouth and Christchurch Hospital
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
St James University Hospital
Leeds
United Kingdom
LS9 7TF

Study participating centre

Sunderland Royal Hospital
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Royal Cornwall Hospital
Truro
United Kingdom
TR1 3LQ

Study participating centre
Homerton University Hospital
London
United Kingdom
E9 6SR

Study participating centre
Royal Derby Hospital
Derby
United Kingdom
DE22 3NE

Study participating centre
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Heart of England NHS Foundation Trust
Birmingham
United Kingdom
B9 5SS

Study participating centre
Imperial College Healthcare NHS Trust
Salton House
St Mary’s Hospital

London
United Kingdom
W2 1NY

Study participating centre
North Bristol Trust
Brunel building
Southmead Hospital
Westbury-on-Trym
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BS10 5NB

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Sponsor type
University/education

Website
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ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial results will be published and disseminated at a later date.

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the study mailbox address (by-band-sleeve@bristol.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	recruiter perspectives	06/01/2014		Yes	No
Protocol article	protocol	11/02/2014		Yes	No
Other publications	most effective operation for adults with severe and complex obesity:	14/03/2014		Yes	No
Other publications	development of a core outcome set	01/01/2015		Yes	No
Results article	qualitative case study results from By-Band	28/12/2015		Yes	No
Other publications	NHS access to bariatric surgery	11/05/2016		Yes	No
Other publications	use of adjustable gastric bands for management of severe and complex obesity:	01/06/2016		Yes	No
Other publications	conveying equipoise during recruitment:	18/10/2016		Yes	No

Other publications	health professionals' and patients' views of the importance of outcomes	01/11/2016		Yes	No
Other publications	core outcome set	29/11/2016		Yes	No
Other publications	adaptation of By-Band randomized clinical trial	01/08/2017		Yes	No
Other publications	costs of bariatric surgery	01/08/2017		Yes	No
Results article	By-Band pilot study results and explanation of By-Band-Sleeve design	01/08/2017		Yes	No
Other publications	enabling recruitment success	01/11/2017		Yes	No
Other publications	EQ-5D-5L to measure health-related quality of life:	18/12/2017		Yes	No
Other publications	QuinteT Recruitment Intervention	01/02/2019		Yes	No
Other publications	micro-costing of procedures	01/02/2019		Yes	No
Other publications	prevalence, and severity, of anxiety and depressive symptoms	03/01/2024	08/01/2024	Yes	No
Results article		31/03/2025	04/04/2025	Yes	No