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SurgiCal Obesity Treatment Study

Submission date	Recruitment status	[X] Prospectively registered
26/09/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2011	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2024	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Bariatric surgery is a type of surgery performed on people who are obese with the purpose of making them lose weight - this includes gastric bypass and gastric banding. It is an increasingly common operation yet the long term benefits and complications are not well known. This study will collect data on every patient in Scotland having weight loss surgery, to monitor their weight, nutrient levels in their blood, whether diabetes gets better or if they develop diabetes in the future, any complications such as wound infections or requiring a second operation, heart attacks, cancer or if they die, and if quality of life improves and they feel more or less anxious or depressed after the surgery. We will follow the patients for 10 years after their surgery.

Who can participate?
Participants will be people undergoing bariatric surgery in Scotland - either in the NHS or private hospitals.

What does the study involve?
The study will follow patients during their normal care before and after surgery. No additional tests will be performed. Results of blood tests and details of any future hospital admissions will be gathered using the data stored in Scottish NHS computer systems. For participants with diabetes, data on their diabetes control, medications and complications will be gathered again from NHS computer systems. Participants will be contacted by post before the operation and annually after the operation to complete a questionnaire on quality of life and also be asked if they have had any complications relate to their surgery. They will be phoned 30 days after surgery to be asked how they are recovering from the surgery.

What are the possible benefits and risks of participating?
There are no benefits or risks to the participants.

Where is the study run from?
The study is run by the University of Glasgow with all NHS and private hospitals providing bariatric surgery in Scotland being involved.

When is the study starting and how long is it expected to run for?
The study will start in January 2012. Participants will be recruited until January 2017 and all participants will be followed up until July 2026.

Who is funding the study?
The National Institute of Health Research Health Technology Appraisal Scheme.

Who is the main contact?
Dr Jennifer Logue
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Contact information

Type(s)
Scientific

Contact name
Dr Jennifer Logue

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Additional identifiers

Protocol serial number
HTA 10/42/02

Study information

Scientific Title
SurgiCal Obesity Treatment Study: a prospective cohort study

Acronym
SCOTS

Study objectives
To establish in a cohort of obese patients who are undergoing bariatric surgery:
1. All cause and cause specific mortality over a mean of 10 years since bariatric surgery.
2. Incidence of cardiovascular disease, cancer and diagnosis of diabetes over a mean of 10 years since bariatric surgery
3. Incidence of acute and chronic postoperative complications. Acute complications, defined as up to three months post surgery, will include surgical site infection; chronic complications will include revisional surgery, plastic surgery and chronic pain.
4. Change in health related quality of life, anxiety and depression over time pre- and post-operatively for a mean of 10 years from date of bariatric surgery.
5. The micronutrient and weight status pre and post-operatively for a mean of 10 years since bariatric surgery.
6. The glycaemic control, lipids, blood pressure, medication prescription, and rate of diabetes

complications (microalbuminuria and renal disease, retinopathy and foot ulceration) in those that have pre-existing diabetes or develop diabetes during a mean of 10 years follow up since bariatric surgery.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/104202
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/55413/PRO-10-42-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted to West of Scotland Reserach Ethics Commitee

Study design
Multi-centre prospective cohort study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
Bariatric surgery (surgical procedures developed for the primary purpose of weight loss currently laparoscopic gastric banding, sleeve gastrectomy and roux-en-y gastric bypass)

2000 patients undergoing bariatric surgery in the NHS and private sector in Scotland, UK, over a 5-year period will be recruited. The participants will be followed up for a mean of 10 years. The mortality, weight, incident type 2 diabetes mellitus (T2DM), coronary heart disease (CHD), cardiovascular disease (CVD), cancer, fractures, nutritional blood markers, anxiety, depression, post-operative complications, revisional surgery rates, health related quality of life, glycaemic control, diabetic complications and diabetes medications will be recorded.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
10-year mortality

Key secondary outcome(s))
In the 10 years following bariatric surgery:
1. Change in weight / body mass index (BMI) from pre-bariatric surgery weight
2. Rate of incident type 2 diabetes
3. Incidence of fatal and non-fatal coronary heart disease, cardiovascular disease, cancer and

fractures
4. Incidence of incidence of nutritional deficiencies
5. Change in incidence of depression and anxiety compared to baseline level pre-operatively
6. Incidence of complications immediately post-operatively and the need for readmission for revisional procedures
7. Change in health-related quality of life compared to baseline level pre-operatively
8. Change in glycaemic control, cardiovascular risk factors, chronic kidney disease (CKD), retinopathy and medications prescribed in patients with diabetes compared to equally obese patient with diabetes who did not have bariatric surgery
9. Cost of the procedure and follow-up (to inform cost-effectiveness analysis)

Completion date
01/07/2026

Eligibility

Key inclusion criteria
Undergoing bariatric surgery in NHS secondary care and private practice in Scotland, UK

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
445

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2014

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
BHF Cardiovascular Research Centre
Glasgow
United Kingdom
G12 9PP

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) (10/42/02)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2024	13/02/2024	Yes	No
Protocol article	protocol	22/05/2015	22/07/2020	Yes	No
Interim results article	Characteristics and health and socioeconomic burden	26/08/2021	31/08/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes