

SurgiCal Obesity Treatment Study

Submission date 26/09/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/09/2011	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/02/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

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
Jennifer.Logue@Glasgow.ac.uk

Study website
<http://www.scotsurgerystudy.org.uk>

Contact information

Type(s)
Scientific

Contact name
Dr Jennifer Logue

Contact details
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United Kingdom
G12 9PP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Research Ethics Committee

Study design

Multi-centre prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

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

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 measure

10-year mortality

Secondary outcome measures

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)

Overall study start date

01/01/2014

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

Age group

Adult

Sex

Both

Target number of participants

2000

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

Scotland

United Kingdom

Study participating centre

BHF Cardiovascular Research Centre

Glasgow

United Kingdom

G12 9PP

Sponsor information

Organisation

NHS Greater Glasgow and Clyde (UK)

Sponsor details

The Tennent Institute

Western Infirmary

38 Church Street

Glasgow

Scotland

United Kingdom

G11 6NT

-

Maureen.travers@ggc.scot.nhs.uk

Sponsor type

Hospital/treatment centre

Website

http://www.nhs.uk/content/default.asp?page=home_Research%20Development

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

Publication and dissemination plan

Added 22/07/2020:

We intend to publish a further three papers:

1. 'Baseline' paper providing a profile of the study cohort ('Health and socio-economic burden in treatment-seeking individuals with severe obesity: profile of the Surgical Obesity Treatment Study (SCOTS) national cohort study' – this paper was recently submitted to the International Journal of Obesity and is currently under peer-review)
2. A paper reporting complications 1 year post bariatric surgery for the SCOTS cohort - it our intention that this paper will be submitted by the end of 2020
3. A paper outlining complications 3 years post bariatric surgery for the SCOTS cohort – it is our intention that this paper will be submitted by summer 2021

Intention to publish date

01/05/2027

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?
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

[Results article](#)

01/01/2024	13/02/2024	Yes	No
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