

# SurgiCal Obesity Treatment Study

<b>Submission date</b> 26/09/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2011	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2024	<b>Condition category</b> 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**  
BHF Cardiovascular Research Centre  
University of Glasgow  
126 University Place  
Glasgow  
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](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](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?
<a href="#">Protocol article</a>	protocol	22/05/2015	22/07/2020	Yes	No
<a href="#">Interim results article</a>	Characteristics and health and socioeconomic burden	26/08/2021	31/08/2021	Yes	No

[Results article](#)

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