

# Excess risk and predictors of fracture/s following bariatric surgery for obese patients in the NHS: a real-world self-controlled case series and cohort study

**First published:** 16/01/2018

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS21907

---

### Study ID

30510

---

### DARWIN EU® study

No

---

### Study countries

 United Kingdom

---

### Study description

**BACKGROUND:** While bariatric surgery is an effective treatment for severe obesity, some research suggests that it might double the risk of bone breaks. However, the data is controversial, and most of the existing studies compare patients undergoing surgery to those not offered such treatments, making the results difficult to interpret. In addition, we do not know which patients who receive bariatric surgery are at highest risk of breaking their bone/s and could be targeted for further bone assessment/s or treatments. The lack of convincing evidence means screening for bone health is not routinely carried out in the NHS.

**AIMS:** We aim to study if there is an increased risk of bone fracture/s following bariatric surgery. In addition, we will look for key factors that can be combined in a risk scoring tool to identify those most likely to suffer such fractures.

**DESIGN/METHODS:** We will use anonymised GP and hospital records to study these associations in real-world clinical practice conditions, and amongst actual NHS patients. According to figures provided by these data sources, >10,900 patients undergoing bariatric surgery for obesity are available for such a study. To avoid the biases mentioned above we will use advanced methods applied in drug and vaccine safety studies (called 'self-controlled case series'), where the risk of fracture in the periods before and after surgery are compared for each patient.

---


## **Study status**

Finalised

## Research institutions and networks

### Institutions

# Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

 United Kingdom

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

NDORMS, University of Oxford

Oxford University Hospitals NHS Foundation Trust  
Oxford, London School of Hygiene and Tropical  
Medicine London

## Contact details

### Study institution contact

Daniel Prieto-Alhambra

daniel.prietoalhambra@ndorms.ox.ac.uk

**Study contact**

[daniel.prietoalhambra@ndorms.ox.ac.uk](mailto:daniel.prietoalhambra@ndorms.ox.ac.uk)

## Primary lead investigator

Daniel Prieto-Alhambra

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/09/2017

Actual: 30/10/2017

---

### Study start date

Planned: 15/10/2017

Actual: 15/01/2018

---

### Data analysis start date

Planned: 15/01/2017

Actual: 02/04/2018

---

### Date of final study report

Planned: 15/06/2019

Actual: 12/07/2019

## Sources of funding

- Other

## More details on funding

NIHR RfPB, University of Oxford

# Study protocol

[PB-PG-1215-20017\\_protocol.pdf](#) (456.82 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

---

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Disease /health condition

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

## **Data collection methods:**

Secondary use of data

---

## **Main study objective:**

Our specific objectives are:1. To study the risk of post-operative fracture risk amongst severely obese NHS patients undergoing bariatric surgery2. To determine key risk factors of post-operative fracture, and to derive a prediction tool the case-finding of high-risk patients at the time of pre-operative bariatric surgery assessment.

# Study Design

## **Non-interventional study design**

Cohort

Other

---

## **Non-interventional study design, other**

Self-controlled case series

# Study drug and medical condition

## **Medical condition to be studied**

Fracture

Gastric bypass

Gastric banding

Gastric stapling

Bariatric gastric balloon insertion

Obesity

# Population studied

## **Short description of the study population**

All patients aged 18 or above registered in a CPRD-linked HES practice with up to standard (UTS) data available between 01/04/1997 and 31/03/2016 and a BMI of 35 or above, undergoing bariatric surgery according to CPRD or HES records were eligible for Objectives 2 and 3.

Only those sustaining 1 or more fracture/s in the observation period (years before or after bariatric surgery) were included for the SCCS (case-only) analysis (Objective 1).

---

## **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
- 

## **Estimated number of subjects**

10989

# Study design details

## **Outcomes**

Our primary outcome will be any osteoporotic fracture/s (excluding skull, face, or digits) in the 5 years following bariatric surgery, with sensitivity analyses using 0-3 and >3 year periods instead. Our secondary outcomes are 1.major fracture (hip, wrist/forearm, spine, and proximal humerus), and 2.peripheral fracture/s (wrist/forearm, ankle, and proximal humerus) in the same time frames. All the proposed outcomes will be ascertained using previously

validated lists of READ codes.

---

### **Data analysis plan**

Self-controlled case series (SCCS) analysis will be used to study the association between bariatric surgery and fracture risk. IRR and 95% confidence intervals will be calculated for incident events observed within the “exposure” period compared to baseline (“non-exposure”) using the SCCS method and assuming a Poisson distribution. Sensitivity analyses will be conducted where the duration of the exposure period will be set at 0-3 and >3 years (post-surgery) respectively. A retrospective cohort design will be used to estimate the incidence rates and cumulative incidence of fracture in the years after bariatric surgery, and to identify key risk factors associated with an increased fracture risk in this population. For the derivation of a clinical prediction tool for post-operative fracture risk, logistic regression analyses will be conducted, where fracture/s in the post-operative risk period will be considered a binary outcome.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data source(s)**

### **Data sources (types)**

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

---

### **Check completeness**

Unknown

---

### **Check stability**

Unknown

---

### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown