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

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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

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Primary lead investigator

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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

10.989

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

Data sources

Data source(s)

Clinical Practice Research Datalink

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