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What groups of people are more prone to complications after Bariatric Surgery, and does acid suppression in the stomach play a role? A mulitregister study

Submission date
20/09/2016

Recruitment status
No longer recruiting

Registration date
04/11/2016

Overall study status
Completed

Last Edited
21/04/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Since obesity (being very overweight) is a growing health problem all over the world, more and more people are having weight-loss surgery because of its proven effects on obesity and related health problems. Having an operation is never risk free, and although weight-loss surgery is relatively safe, there are certain groups of people who are more at risk for complications. Drugs reducing stomach acid are used with varying degrees of success for the purpose of reducing complications, but it’s not clear how great this effect is and who benefits from it. The purpose of this study is to identify groups of patients that are at higher risk for complications and who could benefit most from acid suppression in the stomach.

Who can participate?
Patients that had weight loss surgery (gastric bypass) in Sweden between 2009-2014 and registered in the Scandinavian Obesity Surgery Registry.

What does the study involve?
Data is taken from the Scandinavian Obesity Surgery Register (SOReg) for patients that have had first time gastric bypass surgeries from 2009 through 2014. In addition, matching socio-economic data (that is data describing a person’s age, gender and income for example) is taken from Statistics Sweden and records on proton-pump inhibition prescriptions from the National Board of Health and Welfare's Drug Registry. Analysis is then done on this data, to see whether what type of patient is least likely to develop complications after weight loss surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Department of Surgery and Orthopedics, Lycksele Hospital

When is the study starting and how long is it expected to run for?
October 2016 to May 2017

Who is funding the study?
1. County Council of Västerbotten (Sweden)
2. Umeå University (Sweden)

Who is the main contact?
1. Dr Jeff Wennerlund (public)
Jeff.Wenerlund@umu.se
2. Professor Ulf Gunnarsson (scientific)
Ulf.Gunnarsson@umu.se

Contact information

Type(s)
Public

Contact name
Dr Jeff Wennerlund

ORCID ID
http://orcid.org/0000-0003-0603-751X

Contact details
Lycksele Hospital
Department of Surgery and Orthopedics
Lycksele
Sweden
92182
+46 70-438 1109
Jeff.Wennerlund@umu.se

Type(s)
Scientific

Contact name
Prof Ulf Gunnarsson

Contact details
Department of Surgical and Perioperative Sciences
Umeå Univerisity
Umeå
Sweden
901 87
+46 90-7852909
Ulf.Gunnarsson@umu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PPI-GBP 001

Study information

Scientific Title
Which sub-groups of people are more prone to complications after complications after Bariatric Surgery, and does post-operative prophylaxis with proton-pump inhibition play a role? A multiregister study

Acronym
PPI-GBP

Study objectives
Which combinations of factors predispose to complications after gastric bypass surgery? Does prophylaxis with proton-pump inhibition play a role? What differernces can be acertained from gender, age, existing co-morbidity, BMI, and socio-economic factors? The underlying hypothesis is that certain factors play a role in complications, and if/where proton-pump inhibition has a place in the clinical setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee of Umeå 12/1/2016. Case number 2015/367-31

Study design
Single-site observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Morbid obesity

Interventions
Patient specific gender, age, BMI, existing co-morbidities, socio-economic status, and the presence of proton-pump inhibition is to be collected and compared with the occurrence of post-operative complications in a longitudinal multi-variate study .

After collecting data from the three registers, statistical analyses will be made focusing on the outcome of post-operative complications and their severity (according to the Clavien-Dindo scale) and necessary interventions, if any. Logistic regression models will be used in multi-variate analyses to pinpoint those factors (patient specific age, gender, BMI, pre-existing health problems, occurrence of proton-pump inhibition prophylaxis, and socioeconomic factors) that are associated with higher rates of complications, both as a total rate and for each individual complication. The rate of complications are also controlled against the Drug Registry if the prophylaxis was actually retrieved, or if therapy was prescribed and retrieved for other reasons.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omeprazole, esomprazole

Primary outcome measure
Identification of sub-groups according to age, gender, body mass index measured in body weight (kg)/ body length (m) squared, and pre-existing health problems at baseline that have less post-operative complications and severity thereof (according to the Clavien-Dindo scale) due to prophylaxis with proton-pump inhibition, measured at 30 days and at 1 and 2 years post-operatively.

Secondary outcome measures
Identification of socioeconomic factors at baseline that impact related health problems, the rate of post-operative complications, and occurrence and adherence to proton-pump prophylaxis.

Overall study start date
31/10/2016

Completion date
31/05/2017

Eligibility

Key inclusion criteria
Patients eligible and accepted for primary laparoscopic gastric bypass surgery in Sweden during 2009-2014, and registered in the Scandinavian Obesity Surgery Registry (SOReg).

Participant type(s)

Patient

Age group
All

Sex
Both

Target number of participants
ca 39,000

Total final enrolment
37301

Key exclusion criteria
Participants that do not fulfill inclusion criteria

Date of first enrolment
31/10/2016

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Surgery and Orthopedics, Lycksele Hospital
Hedlundavägen
Lycksele lasarett
Lycksele
Sweden
92182

Sponsor information

Organisation
County Council of Västerbotten (Västerbottens läns landsting)

Sponsor details
Köksvägen 11
Umeå
Sweden

901 89
+46 90-785 0000
landstinget@vll.se

Sponsor type
Government

Website
www.vll.se

ROR
https://ror.org/04xvhsp09

Funder(s)

Funder type
University/education

Funder Name
County Council of Västerbotten (Västerbottens läns landsting)

Funder Name
Umeå Universitet

Alternative Name(s)
Umeå University, Ubmeje universitiähta, Universitas Umensis

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Results and Publications

Publication and dissemination plan
The results are to be published in a peer-review scientific journal. The results will be presented within the local research network, and at national and international scientific conferences.

Intention to publish date

18/01/2020

Individual participant data (IPD) sharing plan

Collecting data from these registers is done under certain conditions. These include that the data may not be shared with a third party, is to be used only according to the purpose stated in the applications and the signed contracts, and that the data is to be erased after the project is completed. Further the information is to be handled in the same manner as patient charts, with utmost confidentiality, with identifying information separate from the raw data and calculation files.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2020	21/04/2020	Yes	No