The effect of bariatric surgery on pharmacotherapy of psychotropic drugs in clinical practice

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55606

Source
ToetsingOnline

Brief title
The effect of bariatric surgery on pharmacotherapy of psychotropic drugs

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
bariatric surgery

Health condition

bariatrische chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Onderzoeksfonds St Antonius ziekenhuis

Intervention

Keyword: antidepressivs, antipsychotics, bariatric surgery, dosage

Outcome measures

Primary outcome

Primairy study endpoint is the change in drug concentrations in plasma (therapeutic drug monitoring) (mg/L) of the psychotropic drug after bariatric surgery (at 1, 3, 6 and 12 months) compared to the drug concentrations in plasma (therapeutic drug monitoring) before bariatric surgery corrected by the dosage and between postbariatric surgery intervals.

Secondary outcome

Secondary study endpoint is:

- the change in mental status, evaluated by the Brief Symptom Inventory (BSI)-questionnaire, after bariatric surgery (at 1, 3, 6 and 12 months), compared to before bariatric surgery and between postbariatric surgery intervals.

Study description

Background summary

Worldwide obesity is a growing problem. In 2016 half of the Dutch population had a body mass index (BMI) of 30 kg/m2 or higher, of which 16% is obese [1]. Morbid obesity (i.e. BMI> 40 kg/m2) is associated with many comorbidities and reduced life expectancy [2]. Beside cardiovascular (26%) and antidiabetic drugs (26%), analgesics (21%), anti-inflammatory and antirheumatic products (non-steroids) (10%), antidepressants (21%), thyroid therapeutics (12%) and drugs for obstructive airway diseases (25%) are commonly used in these patients

[3].

Bariatric surgery or weight-loss surgery is the only treatment for morbid obesity (BMI > 40) that has been shown to produce long term weight loss. In 2017 an estimated 10000 patients underwent bariatric surgery in the Netherlands [4]. Several metabolic surgical techniques are available including restrictive/malabsorptive procedures. Of these techniques, the Roux-Y-gastric bypass (RYGB) and the gastric sleeve are the most commonly performed procedures [4].

Bariatric surgery can influence both the prevalence and incidence of comorbidities (as a result of weight loss), and the pharmacokinetics of drugs (because of bypass or reduction of the stomach and intestines). After bariatric surgery, the use of a drug may be continued or stopped, and the dosage or dosage form may be changed because of adverse drug events or to achieve an optimal therapeutic effect. Currently, little is known about the need to adjust the dosage or dosage form after bariatric surgery. In practice, pharmacists receive a lot of questions about dosages after bariatric surgery from doctors, nurses and patients.

In the Netherlands an estimated 20% of the bariatric surgery population uses one or more psychotropic drugs [3]. Psychotropic drugs include antidepressants, antipsychotics and psychostimulants. There is a lack of systematic information about the number of side effects and/or treatment failure after bariatric surgery in this population. In clinical practice, destabilization of the mental illness occurs regularly in patients using psychotropic drugs after bariatric surgery. This is undesirable given the vulnerability of this patient group. The number of side effects and/or treatment failure after bariatric surgery are missing this population. From one study we know the use of antidepressants decreased with 15% after bariatric surgery [4]. Another study showed that patients taking Selective Serotonin Reuptake Inhibitors (SSRI) were at risk for reduced drug bioavailability one month after RYGB. Multiple studies advice close monitoring of patients using psychotropic drugs after bariatric surgery to evaluate the short-term and long-term safety and efficacy of their drug regimen [6-16]. There is a strong need for guidelines on how to monitor obese patients using psychotropic drugs after bariatric surgery. Currently there is no (national) consensus on whether patients using these drugs need additional monitoring or plasma level evaluations.

The aim of this observational pilot study is to determine the effect of RYGB or Gastric Sleeve on the drug concentrations in plasma (therapeutic drug monitoring) of psychotropic drugs and mental status in patients with psychopathology. Based on these results, preliminary guidance on how to support these patients in clinical practice will be derived.

Study objective

Preliminary guidance on how to support these patients in clinical practice will be derived.

Primary objective is the change in drug concentrations in plasma (therapeutic drug monitoring) (mg/L) of the psychotropic drug after bariatric surgery (at 1, 3, 6 and 12 months) compared to the drug concentrations in plasma (therapeutic drug monitoring) before bariatric surgery and between postbariatric surgery intervals.

Secondary objective is:
- the change in mental status, evaluated by the Brief Symptom Inventory (BSI) questionnaire, after bariatric surgery (at 1, 3, 6 and 12 months), compared to before bariatric surgery and between postbariatric surgery intervals.

Other objectives are:
- exploration of a relationship between the drug concentrations in plasma (therapeutic drug monitoring) of the psychotropic drug and mental status, evaluated by the BSI questionnaire.
- evaluation of the dosage and dosage form during the year after bariatric surgery (at 1, 3, 6 and 12 months).

Study design

It is an observational pilot study.

Study burden and risks

Patients participating in this observational study receive standard care and additional blood sampling and a questionnaire at standard visits. The standard of care constitutes of five visits: before and at 1, 3, 6 and 12 months after bariatric surgery. No extra visits are required provided. Each visit endures 30 minutes.

At the visits before surgery, 6 months and 12 months after surgery, blood sampling is standard care. In this study an extra blood sample will be taken.
At the visits 1 month and 3 months after surgery no blood sampling is standard care. Blood sampling will be done for this study.
Each visit patients will be asked to fill in a questionnaire which requires 8 minutes per questionnaire.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:, - Indication for bariatric surgery (i.e. Body Mass Index (BMI) > 40 kg/m2 or BMI> 35 kg/m2 with additional risk factors) at St Antonius hospital. Bariatric surgery includes the following procedures: laparoscopic (mini-) gastric bypass or laparoscopic sleeve gastrectomy;
- Participant >= 18 years, who uses one of de following psychotropic drugs* for anxiety and depression;
- ASA physical classification II or III;
- Participant is able and willing to sign the Informed Consent form before the screening;
- Intake and follow up by the Dutch Obesity Clinic (in groups sessions);
- Participant suffers from psychopathology and uses one of the following psychotropic drugs:
• Amitriptyline
• Nortriptyline
• Paroxetine
• Sertraline
• Venlafaxine

• Fluvoxamine
• Fluoxetine
• Citalopram

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Known allergy for the administered medicine;
- Pregnancy or breast-feeding. This is an exclusion criterion for bariatric surgery (participants are informed by their surgeon and bariatric nurse). Women of childbearing age who use contraceptive methods are allowed to participate in the study.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	25-02-2019
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-03-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	29544
CCMO	NL65049.100.18