The effect of bariatric surgery on pharmacotherapy of psychotropic drugs

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Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29532

Bron
NTR

Verkorte titel
BARIAP

Aandoening

bariatric surgery
antidepressivs
antipsychotics
dosage

Ondersteuning

Primaire sponsor: St Antonius hospital
Overige ondersteuning: Onderzoeksfonds (budget)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main 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.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 and antidiabetic drugs, analgesics, anti-inflammatory and antirheumatic products (non-steroids), antidepressants, thyroid therapeutics and drugs for obstructive airway diseases 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 [5]. 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. 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 (mini-) 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.

Objective:

Primary objective: To evaluate drug concentrations in plasma (therapeutic drug monitoring) of psychotropic drugs the year after (mini-) RYGB or Gastric Sleeve (at 1, 3, 6 and 12 months) compared to a baseline (before surgery).

Secondary objective: To evaluate mental status, evaluated by the questionnaire Brief Symptom Inventory (BSI), the year after (mini-) RYGB or Gastric sleeve (at 1, 3, 6 and 12 months).

Other:

- To explore whether there is a link between the drug concentrations in plasma (therapeutic drug monitoring) of the psychotropic drug and mental status the year after (mini-) RYGB or Gastric Sleeve.

- To evaluate the dosage and dosage form during the year after bariatric surgery (at 1,3,6 and 12 months).

Study design: Observational pilot study.

Study population: 40 (morbid) obese participants scheduled to undergo bariatric surgery (i.e. Body Mass Index (BMI) > 40 kg/m2 or BMI > 35 kg/m2 with additional risk factors), male and female, aged 18-60 years, who uses one of de following psychotropic drugs* for psychopathology. Bariatric surgery includes the following procedures: laparoscopic (mini-) gastric bypass (RYGB) or laparoscopic sleeve gastrectomy (Gastric Sleeve).

*

• Amitriptyline

• Nortriptyline

• Clomipramine

• Haloperidol

• Clozapine

• Imipramine

• Olanzapine

• Paroxetine

• Risperidone

• Sertraline

• Venlafaxine

• Zuclopenthixol

• Fluvoxamine

• Fluoxetine

• Citalopram

• Quetiapine

- 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 (only patients in groups sessions).

Intervention (if applicable): not applicable

Main study parameters/endpoints:

Primary 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.

Secondary endpoint is:

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

Other endpoints are:

- exploration of a relationship between the plasma concentration of the psychotropic drug and mental status, evaluated by the questionnaire Brief Symptom Inventory (BSI).

- evaluation of the dosage and dosage form during the year after bariatric surgery (at 1, 3, 6 and 12 months).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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. Each visit endures 30 minutes (standard care).

At the visits before surgery, 6 months and 12 months after surgery, blood sampling is standard care. For the purpose of this study an extra blood sample will be taken during routine blood sampling.
At the visits 1 month and 3 months after surgery no blood sampling is standard care. Blood sampling will be done specifically for this study.

Each visit patients will be asked to fill in a questionnaire which requires 8 minutes per questionnaire [5].

The results of the drug concentrations in plasma (therapeutic drug monitoring) of the psychotropic drugs (together with the results of the questionnaire if this may be of use) will be shared with the treating physician, which may be of use for the treatment of the patients.

Onderzoeksopzet

at 0, 1, 3, 6 and 12 months after bariatric surgery

Onderzoeksproduct en/of interventie

n.v.t. Het draait om een observationeel onderzoek met invasieve metingen.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 between 18 and 60 years old;

- 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

• Clomipramine

• Haloperidol

• Clozapine

• Imipramine

• Olanzapine

• Paroxetine

• Risperidon

• Sertraline

• Venlafaxine

• Zuclopenthixol

• Fluvoxamine

• Fluoxetine

• Citalopram

• Quetiapine

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	0
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7311
NTR-old	NTR7527
Ander register	CCMO : 65049

Resultaten