The effect of a gastric bypass on the pharmacokinetics of citalopram

Published: 07-08-2017
Last updated: 15-04-2024

Primary objective: Determine whether a RYGB operation causes a clinically significant decrease in AUC (area under serum concentration-time curve) of citalopram three months after surgery in comparison with the situation before the operation....

Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Observational invasive

Summary

ID

NL-OMON55680

Source
ToetsingOnline

Brief title
CITA II

Condition

- Mood disorders and disturbances NEC
- Gastrointestinal therapeutic procedures

Synonym
Depression, Gastric Bypass

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Vakgroep Chirurgie en Apotheek Franciscus Gasthuis en Vlietland en Maasstad ziekenhuis

Intervention

Keyword: bariatric surgery, citalopram, pharmacokinetics

Outcome measures

Primary outcome

AUC (area under serum concentration-time curve) of citalopram three months after surgery compared to baseline at one month before the surgery.

Secondary outcome

The following pharmacokinetic parameters of citalopram at one and three months postoperative compared to baseline at one month prior to surgery.

- C max (maximal serum concentration) of citalopram
- T max (maximal serum concentration) of citalopram
- T1/2 (half-life) of citalopram
- Trough levels (serum level at time t = 0) of citalopram

Study description

Background summary

Rationale: Psychiatric disorders, including depression, are common in people with morbid obesity. The Roux- and Y gastric bypass (RYGB) operation causes a drastic change in the gastrointestinal tract, which may lead to a change in drug levels. Possibly the changing conditions for drug dissolution and a decrease of absorption in the intestinal area may play a role. Some small-scale studies show that bioavailability decreases in some drugs. However, there is insufficient data available on the effect of a gastric bypass surgery on the pharmacokinetics of citalopram. Further research is needed to adequately map the effect of a RYGB operation on the pharmacokinetics, so that optimal pharmacotherapy treatment can be given to patients after a bariatric procedure.

Study objective

Primary objective: Determine whether a RYGB operation causes a clinically

significant decrease in AUC (area under serum concentration-time curve) of citalopram three months after surgery in comparison with the situation before the operation.

Secondary objectives:
Validation of the pharmacokinetic model of citalopram (based on data from the CITA I study) in obese and bariatric patients with the optimal sampling strategy created from this data. Determine whether the citalopram pharmacokinetic parameters Cmax (maximal concentration), Tmax (time of maximal serum concentration) and T1/2 (half-life)) of citalopram before and after surgery differ significantly after one and three months compared to the situation before RYGB. Compare the citalopram trough levels after one and three months to the trough levels before the RYGB.

Study design

Study design: pre- / post study; Prospective, observational research.

Study burden and risks

The burden of participation in the study is high for the participants. In total, they will spend three days in the Maasstad Ziekenhuis or the Franciscus Gasthuis. The preoperative visit and the visit one month postoperatively are additional visits for the patient. Participation in this study three months postoperatively is combined with the regular follow-up of the surgeon and dietician.

De bloedafname zal plaatsvinden volgens de venapunctie methode of de venflon methode. Hieronder zullen de twee methodes worden toegelicht.

Venapunction method
On the research day the participant will receive a venapunction at three different times during each research day, 4 ml of blood will be taken at these times. In this way the participant is not burdened with a venflon and there is no risk of clogging of the venflon.

Venflon method
On the research day the participant will receive a venflon. In this way, the participant only has to be injected once. Blood samples are taken via the venflon. 4 ml of blood will be taken at three different times during each research day.

Risks of participation in the research are small for the participants: research is done with a registered drug whose dose and composition will not be adjusted for the study. Chances of AEs and SAEs are not greater than in standard

treatment. The results of this research may provide data that may lead to new pharmacological insights and further scientific research.

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

- Age of 18 years and older
- The patient uses citalopram daily
- The patient is prescribed citalopram at least 2 month before included in the studie, and uses the same dose for at least one week before bloodsampling
- The patient is on the waitinglist for a primairy Roux- and Y gastric bypass
- The patient is a patient in the Maasstad ziekenhuis or the Franciscus Gasthuis en Vlietland
- The patient participates voluntary in the study

- The patient has read and understands the information letter and has signed the consent form

Exclusion criteria

- Persons who have previously undergone a bariatric procedure
- Persons with an impaired liver and/or kidney function (ALAT> 80 U / l; gamma GT> 100 U / L; MDRD <50 ml / min)
- Women who are pregnant or are breastfeeding
- Patients who are incompetent
- The participant is on the waiting list for a mini bypass, gastric band, gastric sleeve or biliopancreatic diversion

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2017
Enrollment:	19
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-08-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	15-02-2023
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
CCMO	NL61852.101.17