Pharmacokinetics of Paracetamol before and after Roux-en-Y gastric bypass

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25518

Source
Nationaal Trial Register

Brief title
PAPAYA

Health condition

Morbidly obesity

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: No funding

Intervention

Outcome measures

Primary outcome

Pharmacokinetics of paracetamol after a single oral dose of 1000 mg before and after RYGB

Secondary outcome

Pharmacokinetics of the metabolites paracetamol glucuronide, paracetamol sulfate,

paracetamol mercaptopurate and paracetamol cysteïne.

Additional secondary end points are aspartate aminotransferase, alanine aminotransferase, gamma-glutamyltransferase and bilirubin values before, after 6h and 24h after a single oral dose of 1000 mg PCM before and after RYGB.

Study description

Background summary

The number of bariatric procedures performed in The Netherlands is increasing, especially Roux-en-Y gastric bypass (RYGB). Little is known about the effect of RYGB on the pharmacokinetics of drugs, neither the surgery procedure itself nor the loss of weight in the long term. It is unclear how to dose drugs both shortly and long after the surgery. Paracetamol (PCM) is a widely used analgesic used by patients because of RYGB, but it can also be used for pother reasons. PCM is a potential hepatotoxic drug when used in too high dosages.

Morbid obesity, RYGB surgery and the normalization of weight affect the pharmacokinetics of PCM, including both absorption and elimination, as well as the formation of toxic metabolites. A higher dosage of PCM could be considered to overcome the lower maximal concentration (Cmax) and total exposure (AUC), but this option may be limited by the additional formation of toxic metabolites. This is why all these aspects will be combined in this research to understand the pharmacokinetics of PCM before and after RYGB surgery.

The objective of this study is to assess the effect of a RYGB on the pharmacokinetics of a single dose of 1000 mg PCM before the surgery, within one month after the surgery and 6 months after the surgery.

This study is an open-label, longitudinal pharmaceokintics study. 20 morbidly obese patients will be included, who are planned to undergo a Roux-en-Y gastric bypass surgery. Furthermoe, 8 healthy non-obese volunteers will be included to assess the pharmacoekintics of a single oral dose of 1000 mg PCM.

Study objective

RYGB affects pharmacokinetics of PCM within one month and after 6 months after the surgery.

Study design

Study planned on 1 February 2020

Intervention

Single oral dose of PCM 1000 mg

Contacts

Public
Albert Schweitzer ziekenhuis
Cedric Lau

0786523213
Scientific
Albert Schweitzer ziekenhuis
Cedric Lau

0786523213

Eligibility criteria

Inclusion criteria

- At least 18 years old
- On the waiting list of getting a RYGB
- Mentally competent
- Provided informed consent

Exclusion criteria

- Undergoing different types of bariatric surgery, such as gastric band, gastric sleeve, mini gastric bypass or revision RYGB
- Previously undergone a gastric surgery, such as gastric band, RYGB or gastric sleeve
- Liver failure
- Taken PCM < 24h before blood sampling at t=0
- Allergy or intolerance for PCM
- Not being able to take PCM orally

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2020
Enrollment:	28
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	11-01-2020
Application type:	First submission

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
NTR-new	NL8280
Other	METC EMC : MEC-2019-0534

Study results

Summary results
N/A