Ursodeoxycholic acid for the prevention of symptomatic gallstone disease after Roux-en-Y gastric bypass and sleeve gastrectomy

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20653

Source
Nationaal Trial Register

Brief title
UPGRADE

Health condition

Gastric bypass; bariatric surgery; gallstone disease

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC, Amsterdam, Netherlands
Source(s) of monetary or material Support: Funding is provided by:
- ZonMW (The Netherlands Organisation for Health Research and Development) Grant number 848015003
- Zambon the Netherlands BV

Intervention

Outcome measures

Primary outcome

The primary endpoint of this study is symptomatic gallstone disease after 24 months, defined as hospital admission or hospital visit for symptomatic gallstone disease. Hospital visit is a condition, because all patients with noteworthy symptoms will eventually visit the hospital. Mild and self-limiting complaints are not a large burden to the health care system or to the patient, and usually gallstone involvement is not objectified in these patients.

Symptomatic gallstone disease is defined as biliary disease (biliary pancreatitis, acute cholecystitis, choledocholithiasis, cholangitis, or biliairy colics).

Secondary outcome

1. The development of gallstones/sludge on ultrasound at 24 months in the gallstone negative group at baseline.

2. Presence of gallstones/sludge on ultrasound at 24 months
3. Number of cholecystectomies in the intervention and the placebo group.

4. Side-effects of UDCA.

5. Therapy compliance.

6. Quality of life, cost-effectiveness, cost-utility and budget impact analyses.

Study description

Background summary

The number of bariatric interventions for morbid obesity is increasing rapidly. Rapid weight loss is a major risk factor for gallstone development. Approximately eleven percent of patients who underwent Roux-en-Y gastric bypass develop symptomatic gallstone disease. After sleeve gastrectomy similar incidences of symptomatic gallstone disease are reported. Gallstone disease can lead to severe complications and often requires hospitalization and surgery. Ursodeoxycholic acid (UDCA) prevents the formation of gallstones after bariatric surgery. However, randomized controlled trials with symptomatic gallstone disease as primary endpoint have not been conducted. Currently, major guidelines make no definite statement about postoperative UDCA prophylaxis and most bariatric centres do not prescribe UDCA.

We will conduct a randomized, placebo-controlled, double-blind multicentre trial. The study population consists of consecutive patients undergoing Roux-en-Y gastric bypass or sleeve gastrectomy in the MC Slotervaart, OLVG West and MC Zuiderzee Lelystad. Patients will receive a preoperative ultrasound, randomisation will be stratified for patients already having gallstones and type of surgery. The intervention group will receive UDCA 900mg once daily for six months. The placebo group will receive similar-looking placebo tablets. The primary endpoint is symptomatic gallstone disease after 24 months, defined as admission or hospital visit for symptomatic gallstone disease. Secondary endpoints consist of the development of gallstones on ultrasound at 24 months and side-effects of UDCA. Cost-effectiveness, cost-utility and budget impact analyses will be performed with costs per patient with poor outcome, costs per quality adjusted life year, respectively total reimbursement as primary outcomes.

Study objective

Rapid weight loss is a major risk factor for gallstone development. Approximately eleven percent of patients who underwent Roux-en-Y gastric bypass develop symptomatic gallstone disease. After sleeve gastrectomy similar incidences of symptomatic gallstone disease are reported. Gallstone disease can lead to severe complications and often requires hospitalization and surgery. Ursodeoxycholic acid (UDCA) prevents the formation of gallstones after bariatric surgery. However, randomized controlled trials with symptomatic gallstone disease as primary endpoint have not been conducted. Currently, major guidelines make no definite statement about postoperative UDCA prophylaxis and most bariatric centres do not prescribe UDCA.

This study is designed to provide evidence regarding the prophylactic use of UDCA in preventing symptomatic gallstone disease after bariatric surgery.

Study design

Regular care includes follow-up appointments at 2 and 6 weeks, 4, 6, 12 and 24 months. The study ends after 24 months of follow-up.

Intervention

Ursodeoxycholic acid is an artificial bile acid that reduces the ratio of cholesterol to bile salts plus phospholipids in bile, causing desaturation of cholesterol saturated bile. In this study it is prescribed as tablets of 450mg, 2 tablets once daily or 1 tablet twice daily. The placebo will be similar in look but without active ingredients.

Prior to surgery, an ultrasound of the gallbladder is performed in each patient. Randomization is stratified for the presence of gallstones and type of surgery.

Contacts

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Eligibility criteria

Inclusion criteria

- Scheduled to undergo Roux-en-Y gastric bypass or sleeve gastrectomy for morbid obesity

- An intact gallbladder

Exclusion criteria

- Symptomatic gallstone disease already present before RYGB

- Prior bariatric surgery

- Prior gallbladder surgery

- Ascertained or presumptive hypersensitivity to active or excipient ingredients of UDCA.

- Inflammatory bowel disease and other conditions of the small intestine and liver which may interfere with enterohepatic circulation of bile salts (ileal resection and stoma, extra and intra-hepatic cholestasis, severe liver disease)

- Intake of investigational drug within the last 30 days before the screening

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2017
Enrollment:	980
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49056
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5954
NTR-old	NTR6135
CCMO	NL59657.048.16
OMON	NL-OMON49056

Study results