Ursodeoxycholic acid for the prevention of symptomatic gallstone disease after Roux-en-Y Gastric Bypass and Sleeve Gastrectomy.

Published: 09-11-2016
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This study is designed to provide evidence regarding the prophylactic use of UDCA in preventing symptomatic gallstone disease after RYGB and Sleeve Gastrectomy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gallbladder disorders
Study type	Interventional

Summary

ID

NL-OMON49056

Source
ToetsingOnline

Brief title
UPGRADE

Condition

- Gallbladder disorders

Synonym
Gallstone disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW programma Goed Gebruik

Geneesmiddelen,Zambon

Intervention

Keyword: Gallstones, Roux-en-Y gastric bypass, Sleeve Gastrectomy, Ursodeoxycholic acid

Outcome measures

Primary outcome

The primary endpoint is the difference between the two groups in symptomatic gallstone disease after 24 months, defined as admission or hospital visit for symptomatic gallstone disease.

Secondary outcome

Secondary endpoints consist of the development of gallstones on ultrasound at 24 months, side-effects of UDCA and cost-effectiveness, cost-utility and budget impact analyses

Study description

Background summary

The number of bariatric interventions for morbid obesity is rapidly increasing in the Netherlands. 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. Similar rates of gallstone disease are reported in patients who underwent Sleeve Gastrectomy. 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.

Study objective

This study is designed to provide evidence regarding the prophylactic use of UDCA in preventing symptomatic gallstone disease after RYGB and Sleeve

Gastrectomy.

Study design

Randomized, placebo-controlled, double-blind multicentre trial.

Intervention

The intervention group will receive UDCA 900mg once daily for six months. The placebo group will receive similar-looking placebo tablets.

Study burden and risks

Most of the procedures required for this study are similar to the current standard care. Additional measures include a gallbladder ultrasound preoperatively and after 24 months, the prescription of investigational product (UDCA or placebo) for 6 months, and several questionnaires that have to be filled in at 5 different time points. The risks of this study are minimal. UDCA has been used for several decades in the treatment of gallstone disease and other biliary diseases, and is known to have only few side effects and no serious side effects.

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

* 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 ursodeoxycholic acid.
* 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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2017
Enrollment:	980
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ursochol
Generic name:	Ursodeoxycholic acid
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-12-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2017

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-03-2019

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20653
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-003245-29-NL
CCMO	NL59657.048.16
OMON	NL-OMON20653

Study results

Date completed:	06-11-2020

Actual enrolment: 985

Summary results
Trial is onging in other countries