Lactose intolerance and malabsorption after Roux-en-y gastric bypass surgery

Published: 18-07-2016
Last updated: 16-04-2024

Primary objective: to objectify the influence of Roux-en-y gastric bypass surgery on the prevalence of lactose intolerance / malabsorption.Secondary objective: To determine the usability of the lactose hydrogen breath test, the lactose tolerance...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malabsorption conditions
Study type	Observational invasive

Summary

ID

NL-OMON47896

Source
ToetsingOnline

Brief title
LAIRY

Condition

- Malabsorption conditions
- Bone, calcium, magnesium and phosphorus metabolism disorders
- Gastrointestinal therapeutic procedures

Synonym
Milksugar intolerance

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Gasthuis
Source(s) of monetary or material Support: Stichting klinisch wetenschappelijk onderzoek slotervaartziekenhuis

Intervention

Keyword: gastric bypass, Lactose intolerance, Malabsorption, Roux-en-y

Outcome measures

Primary outcome

Primary outcome: Prevalence and intensity of lactose intolerance and

malabsorption 1 year after Roux-en-y gastric bypass surgery.

Secondary outcome

Secondary outcome: Usability and inter-test variability of the lactose hydrogen

breath test, the lactose tolerance test and lactose intolerance questionnaire 1

year after Roux-en-Y gastric bypass.

Study description

Background summary

A common problem after Roux-en-y gastric bypass surgery is an insufficient calcium intake and uptake. Frequently vitamin D deficiencies and elevated PTH levels are found. This could eventually lead to osteoporosis. Sufficient intake of dairy, which is the primary source of calcium in a Western diet, after RYGB is desired.
Unfortunately, a proportion of patients experience gastro-intestinal complaints after the consumption of dairy products after RYGB. Exact numbers are unknown. It is of interest to determine the prevalence and pathophysiology of this (secondary) lactose intolerance / malabsorption after RYGB.

Study objective

Primary objective: to objectify the influence of Roux-en-y gastric bypass surgery on the prevalence of lactose intolerance / malabsorption.
Secondary objective: To determine the usability of the lactose hydrogen breath test, the lactose tolerance test and a lactose intolerance questionnaire after Roux-en-Y gastric bypass.

Study design

This is a case control study.
Using a questionnaire, the prevalence of the reported gastro-intestinal complaints will be determined. Lactose malabsorption will be objectified/ determined using the lactose hydrogen breath test and lactose tolerance test. A group of patients more than 1 year after RYGB and a non-surgery group of patients with morbid obesity will be tested.

Study burden and risks

Completion of the questionnaire is not stressful and can be done in less than 5 minutes.
Patients with unexplained gastro-intestinal complaints can benefit of participation in this study when positive test results indicate lactose intolerance, dietary alterations can be made. There are no other benefits for participants.
The lactose hydrogen breath test and lactose tolerance test are considered safe tests and are usually well tolerated. The lactose tolerance test requires the testing of capillary blood samples obtained via finger-prick.
Patients with lactose intolerance can experience complaints of nausea, vomiting, bowel cramps, flatulence and diarrhea after intake of the lactose/glucose drink required for testing.

Contacts

Public
Spaarne Gasthuis

Spaarnepoort 1
Hoofddorp 2134TM
NL
Scientific
Spaarne Gasthuis

Spaarnepoort 1
Hoofddorp 2134TM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients more than 1 year after Roux-en-y gastric bypass surgery and patients with morbid obesity who whether or not opt for Roux-en-y gastric bypass.

Exclusion criteria

- Diabetes mellitus
- Recent use of probiotics and/or antibiotics (<28 days)
- Gastro-intestinal disease/surgery other than RYGB surgery
- Consumpion of >60 gram (= 6 units) alcohol/day

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2018
Enrollment:	168
Type:	Actual

Medical products/devices used

Generic name:	lactose hydrogen breath test
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-07-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL57680.048.16

Study results

Date completed:	25-11-2019
Actual enrolment:	168