

Vitamin Deficiencies and Supplementation in Morbidly obese

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vitamin related disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38253

Source

ToetsingOnline

Brief title

VITAAL 2

Condition

- Vitamin related disorders

Synonym

vitamin deficiencies

Research involving

Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: eigen financiering

Intervention

Keyword: morbidly obese, roux-en-y Gastric Bypass, vitamin deficiencies

Outcome measures

Primary outcome

Number of vitamin deficiencies

Number of outpatient visits per patient

Reduction in number of vitamin B12 deficiencies after treatment with multivitamin tablets.

For precise details, see the research (Chapter 4 aims of the study)

Secondary outcome

For precise details, see the research (Chapter 4 aims of the study)

Study description

Background summary

The number of bariatric surgeries has increased the past decades. There are several types of bariatric surgery; the most important are the gastric band, Gastric Sleeve and Roux - en-Y Gastric Bypass (RYGB). The RYGB is in our centre the most common type of bariatric surgery. The effect of the RYGB is a combination between malabsorption and restriction. In addition to the benefits that entails RYGB (weight reduction, improvement of co-morbidities, improved quality of life, etc.) there are also disadvantages, including vitamin deficiencies. Despite the advice to use 150% RDA of multivitamins, additional supplementation of in particular iron, vitamin B12 , Folic Acid , Vitamin D and Calcium are necessary. Almost 40% of the postoperative bariatric patients who visit our outpatient department are coming for examination or treatment of a vitamin or mineral deficiency. Any reduction in the number of deficiencies would not only reduce the morbidity of the patients but also the pressure on postoperative outpatient clinic. Based on literature on vitamin and mineral deficiencies a specifically multivitamin was developed for patients with Gastric Band, GS and RYGB . This multivitamin is freely available to all patients since 2010. In this multivitamin, the proportions of vitamins are adjusted so that the risk of shortages should be reduced and high values should

be avoided.

Study objective

The main objective is to optimize the supplementation of vitamins and minerals to prevent postoperative deficiencies after MB / RYGB or GS on the long term. We also examined whether the number of outpatient visits, blood tests, and costs can be reduced. Finally, this study compares the effect multivitamin tablets and vitamin B12 injections on the development of vitamin B12 deficiencies. For precise details, see the research protocol (Chapter 4 aims of the study)

Study design

The majority of the study will be retrospectively on patients who underwent in the past MB / gastric sleeve or RYGB.

The treatment of vitamin B12 deficiencies with tablets or injections (hydroxocobalamin) will be done prospectively.

For precise details, see the research protocol (Chapter 5 methods)

Study burden and risks

All visits will be within the regular care as that comes standard after bariatric surgery.

Contacts

Public

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NL

Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients who underwent RYGB; Patients who developed a vitamin B12 deficiency postoperatively

Exclusion criteria

Creatinine > 150 micromol / L; Liver enzymes > 2 times the upper limit; Previous operations on the gastrointestinal tract (except RYGB); Intercurrent disease; Gastrointestinal disease; psychiatric illness; known pregnancy

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2014
Enrollment:	50

Type: Actual

Medical products/devices used

Product type: Medicine
Brand name: Hydroxocobalamine
Generic name: Hydroxocobalamine
Registration: Yes - NL intended use

Ethics review

Approved WMO
Date: 03-01-2014
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO
Date: 05-06-2014
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2013-004835-60-NL
CCMO	NL47058.091.13