Vitamine suppletion by morbide obase patient

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Optimization of the supplementation of vitamins and minerals1. In patients who received a gastric banding for treatment for their morbid obesitya. Reduction of iron deficiencyb. Reduction of Vitamin B12 deficiencyc. Reduced Vitamin D deficiency2. In...

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

Summary

ID

NL-OMON39275

Source
ToetsingOnline

Brief title
Vitaal study

Condition

- Malabsorption conditions
- Gastrointestinal therapeutic procedures

Synonym
Vitamin deficiencies

Research involving
Human

Sponsors and support

Primary sponsor: Alysis Zorggroep
Source(s) of monetary or material Support: Eigen onderzoeksfonds

Intervention

Keyword: Gastric band, Gastric bypass, Morbide obeses, Vitamin-deficiency, Vitamine deficiencies

Outcome measures

Primary outcome

Number of deficiencies for folic acid, vitamin B12, iron vitamin D and calcium

Secondary outcome

Deficiencies in other vitamins and minerals that are measured;

Vitamin A, Vitamin B1, Magnesium, Vitamin B6, Ferritin, Zinc, Phosphate

Study description

Background summary

International literature provides many recommendations about the optimal treatment and prevention of several common deficiencies in vitamins and minerals. Unfortunately, these opinions are often limited to a small number of examined nutrients and turn them into practice in many patients not enough. On the basis of evidence-based literature on vitamins and minerals, a manufacturer produced a multivitamin specifically designed for patients with a gastric band or a RYGB. In these preparations, the proportions are adjusted so that the risk of shortages should decrease and on the other hand, too high in nutrients should be avoided.

Study objective

Optimization of the supplementation of vitamins and minerals
1. In patients who received a gastric banding for treatment for their morbid obesity
a. Reduction of iron deficiency
b. Reduction of Vitamin B12 deficiency
c. Reduced Vitamin D deficiency

2. In patients with a RYGB to undergo treatment for their morbid obesity
a. Reduction of iron deficiency

b. Reduction of Vitamin B12 deficiency
c. Reduced Vitamin D deficiency
d. Reduction of Folate deficiency
e. Reduction of calcium deficiency

Study design

Start of study;
The manufacturer of the tablets produced 400 sets of multivitamins (each set a year's supply), each set with a unique number on each box. In total there are:
1. 100 Sets New MVM for the gastric band
2. 100 Sets New MVM for the RYGB
3. 200 Sets Basic MVM for a control group and a control gastric band patients RYGB patients.

The key to this series is made by the manufacturer, and given to our independent pharmacist. This pharmacist will be responsible for control and handout of multivitamins. Interim analysis is performed by the same pharmacist for every 50 patients who postoperatively have a measurement carried out. The pharmacist will break the key on these moments and carry out an interim analysis. If the outcomes are significantly different to high levels of vitamins or minerals are found (above normal) it will immediately be fed back to both the principal investigator. The latter is however not expected.

Pre-operative patients:
Two weeks prior to the information session for operation that patients receive 3 months for their operation the patient is contacted by telephone by the attending surgeon. If the patient is positive about the study, the patient will receive more information by letter.
At the information session the patient has a personal conversation with his surgeon. At present, the patient is asked whether he wishes to participate in the study and asked to sign an Informed Consent (IC) (in duplicate). At the CRF, the basic data of the patient are recorded. From this point the patient will be considered included and receives a number which corresponds to a set of multivitamins. In total, four groups emerge as:

Group 1: Banding with MVM's new
Group 2: Banding with MVM's current
Group 3: RYGB with MVM's new
Group 4: RYGB with MVM's current

The same day the standard preoperative lab will be withdrawn.
If there are deficits or other abnormalities are found, patients are seen by the endocrinologist. This will be the patients preoperatively suppletion to make up a normal level.

Operation:

On the day of surgery only weight is recorded, operative time and blood loss and possible complications

6 Months control
During this audit, patients will get another set of multivitamins for their second half year. In addition, there is a fasting blood test done. Also this is a regular blood test. On the CRFs are the current weight, Fat%, medication and decrease co-morbidity recorded
If there are deficits or other abnormalities are found, patients are seen by the endocrinologist. This will be the patients preoperatively suppletion to make up a normal level.

12 Months Control
This control is similar to that of 6 months. According to standard protocol a blood test is done. CRFs are the current weight, Fat%, medication and decrease co-morbidity recorded
If there are deficits or other abnormalities are found, patients are seen by the endocrinologist. This will be the patients preoperatively suppletion to make up a normal level.

Besides these studies, we will keep track of what the cost in terms of correcting deficiencies. This will be a cost-benefit analysis

Intervention

Standard multivitamin vs. optimal multivitamin

Study burden and risks

Burden; Patient must complete a questionnaire three times (3 times 5 minutes).

Risks; too high levels of vitamins and minerals. However, this risk is lower than when using regular multivitamins. In addition, patients frequently pinned to verify this
LuisterenFonetisch lezen

Contacts

Public
Alysis Zorggroep

Wagnerlaan 55
Arnhem 6800 TA
NL

Scientific
Alysis Zorggroep

Wagnerlaan 55
Arnhem 6800 TA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients between 18-65 years on the waiting list for RYGB and gastric band

Exclusion criteria

1. Creatinine> 150micromol / L
2. Liver enzymes> 2 times the upper limit
3. Previous surgery on the gastrointestinal tract
4. Diseases influencing absorption
5. Gastrointestinal Diseases
6. Psychiatric illness
7. Drugs that affect the bone metabolism
8. Known pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	15-03-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-08-2017
Application type:	Amendment
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
CCMO	NL33956.091.10