Iron absorptiontrail after Roux- en -Y Gastric Bypass

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Evaluate if ironabsorption is disturbed after a RYGB, which leads to a insufficient treatment of oral ironsuppletion. Analyse if failure of oral ironsuppletion is predictable at baseline (T=0) in the absorption test.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Iron and trace metal metabolism disorders
Study type	Observational invasive

Summary

ID

NL-OMON40906

Source
ToetsingOnline

Brief title
Ironabsorption trial

Condition

- Iron and trace metal metabolism disorders

Synonym
anemia, Irondeficiency

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: eigen financiering afdeling

Intervention

Keyword: absorption, iron, roux- en -y gastric bypass

Outcome measures

Primary outcome

Iron values in the blood before and 1,2,3,4,5 and 6 hours after the

administration of oral ironreplacement in micrograms / dl.

Secondary outcome

The difference between pre- and postoperative absorptionvalues.

Study description

Background summary

There are indications that the absorption of oral iron supplementation is reduced after a RYGB. Nevertheless, oral preparations are used as standard therapy for iron deficiency, even in patients who underwent a RYGB. To take a better look at the absorption of iron after a gastric bypass, we'll perform an ironabsorption test in the period pre- and postoperative. This part of the study will be performes only in the Rijnsate Hospital in Arnhem.
Hyopthesis: when the ironabsorption test shows major differences in absorption after a RYGB, we may predict in the future the effectiviness of oral ironsuppletion.

Study objective

Evaluate if ironabsorption is disturbed after a RYGB, which leads to a insufficient treatment of oral ironsuppletion.
Analyse if failure of oral ironsuppletion is predictable at baseline (T=0) in the absorption test.

Study design

Prospective monocentre study (only in the Rijnstate Hospital Arnhem).
Twenty-four patients will perform an ironabsorption test pre- and postoperatively. There will be 2 groups (each group contains 12 patients).

Preoperatively: group 1 receives a daily dose of ferrous fumarate (600mg) and

group 2 receives a daily dose Losferron (1390mg).
Before intake of the medicins, a fasting bloodsample is taken (baseline), serum iron including ferritin, transferrin and transferrin saturation will be measured. After intake of losferron/ferrous fumarate blood samples will be taken 1, 2, 3, 4, 5 and 6 hours after intake, using a drip. An increase of 80 microgram/l is representative for a sufficient ironabsorption.

Postoperatively; one month postoperatively the same absorption test will be repeated in the same patients.

Study burden and risks

Participants in this study will not experience a direct benefit. The study was set up to optimize iron suppletion in patienst who developed a irondeficiency after RYGB. Irondeficiency is frequently seen after a RYGB. A ironabsorption test will be performed. Participants receive in the periode before and after the operation a single dose Losferron / ferrous fumarate. An infusion is aplied. Blood will be collected from the applied infusion, in total 14 times: 7 times preoperatively and 7 times postoperatively

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

Patients who are eligible for a primary Roux- en -Y gastric bypass and have no pre-existing iron deficiency (serum ferritin of 20-200 micrograms / L), age between 18-65 years.

Exclusion criteria

-bloodtransfusion one month before and in the study period
-the use of ironcontaining nutritional supplements, except our standardized multivitamin supplements.;-decreased function of the kidney with a GFR of < 30ml/min and/or serum kreatinin below 50micromol/L;-Hb < 7,4 mmol/L in females and Hb < 8.4mmol/L in males;- accumulation of iron;- iron diseases;- hypersensitivity for one of the medicinal products ;- psychiatric illness;-pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-09-2014
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ferrous fumarate
Generic name:	ferrous fumarate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	ferrous gluconate
Generic name:	losferron
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-06-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-07-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-12-2014
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
EudraCT	EUCTR2014-002323-10-NL
CCMO	NL49646.091.14