Optimizing iron suppletion after Roux-en-Y Gastric Bypass

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Part 1:Prospective evaluation of serum ferritin levels after suppletion with ferrous fumarate, Losferron or Ferinject in patients with iron deficiency after primary RYGB. Which therapy is the most effective one to replace ironstorage?We also analyse...

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

Summary

ID

NL-OMON41030

Source
ToetsingOnline

Brief title
Irontrial

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

Intervention

Keyword: Iron

Outcome measures

Primary outcome

Part 1:

Serum ferritin, iron, hemoglobin, transferrin saturation, and transferrin after 6, 12 and 52 weeks after administration of ferrous fumarate, Losferron or Ferinjet.

Part 2:

Iron values in the blood before and 1,2,3,4,5 and 6 hours after the administration of oral ironreplacement in micrograms / dl. The difference between pre- and postoperative absorptionvalues.

Secondary outcome

Part 1:

Evaluate patients' preference of the route of administration : administered orally (ferrous fumarate / Losferron) or intravenously (Ferinject).

Study description

Background summary

Part 1:

The number of people with morbide obesitas in the Western World has increased a lot the past 10 years. During this period the number of bariatric procedures in the Netherlands increased from a 1000 interventions in the year 2000 to 9000 interventions in 2012. Bariatric procedures can be divided in restrictive techniques, malabsorptieve techniques or a combination of both. The Adjustable Gastric Band (AGB) an the Gastric Sleeve (GS) are restrictive techniques, the Roux-en-Y gastric bypass (RYGB) is a combined technique with a average weight loss of 60-70 %. Unfortunately vitamin and mineral deficiency is a consistent effect of the malabsorptie and reduced intake after the surgery. Iron deficiency is known in 14-66% of the cases in the first two years after surgery. A postoperative identified irondeficiency will be supplied with oral ironsupplements. There are three preparations who are used worldwide. The most common oral preparations are ferrous fumarate and Losferron (ferrogluconaat). When deficiency doesn*t improve with oral supplements patients will be treated with Ferinject (iron(III)carboxymaltose).
It is of importance to treat an irondeficiency to prevent a microcytic anemia and fatigue caused by irondeficiency.
The risk of developing iron deficiency anemia after RYGB is the most high in premenopausal women.

Part 2:

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 performed only in the Rijnsate Hospital in Arnhem.
Hypothesis: 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

Part 1:

Prospective evaluation of serum ferritin levels after suppletion with ferrous fumarate, Losferron or Ferinject in patients with iron deficiency after primary RYGB. Which therapy is the most effective one to replace ironstorage?
We also analyse the interval between initiation of therapy and adequate correction of iron deficiency.

Part 2:

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

Part 1:

A prospective radomised controlled trial will be performed with 240 patients who underwent a primary RYGB and postoperatively develop a irondeficiency (ferritin < 20 microgram/l). Women (group 1) and men (group 2) will be seperated in 2 groups of 120 patients. Irondeficiency is identified during the postoperative follow-up (standard follow-up moments in our centre: 6,12,24 and 36 months).
Group 1 and 2 will be randomised in 3 treatment groups: treatment with ferrous fumarate, losferron (ferrogluconate) or ferinject.

- Group 1A: irondeficiency in this women will be corrected by ferrous fumarate 200mg 3 times daily.
- Group 1B: irondeficiency in this women will be corrected by losferron 695mg 2 times daily.
- Group 1C: irondeficiency in this women will be corrected by a single shot Ferinject, dosage will be examined for each patient individually. The intravenous injection will be performed in the cilinical day centre.
- Group 2A: irondeficiency in this men will be corrected by ferrous fumarate 200mg 3 times daily.
- Group 2B: irondeficiency in this men will be corrected by losferron 695mg 2 times daily.
- Group 2C: irondeficiency in this men will be corrected by a single shot Ferinject, dosage will be examined for each patient individually. The intravenous injection will be performed in the cilinical day centre.

The effect of different ironsuppletions on the serum ferritin will be evaluated 6 weeks after starting treatment. When ironlevels awill not be normalized, treatment will be continued and follow-up will be performed 12, 26 and 52 weeks after starting therapy, including blood samples for ferritin.
During the appointments a questionairre will be filled in to evaluate the route of administration preference of the patient (oral suppletion vs. intravenous injection).

Part 2:

Prospective monocentre study (only in the Rijnstate Hospital Arnhem). Twenty-four patients will perform an ironabsorption test pre- and postoperatively. There will be randomized between 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

Part 1:

Participants who received oral iron supplementation in this study, will not experience any direct benefit, because it is the standard treatment for irondeficiency.
The study is designed to optimize the treatment for irondeficiency developed after RYGB and to evaluate the most preferred suppletionmethod for the patient. Patients who have an irondeficiency are treated with ferrous fumarate or Losferron (group 1A, 1B and 2A and 2B).
Group 1C, and 2C are treated with Ferinject. These patients (group C) may have the advantage that after one intravenous injection the serum ferritin normalizes and no further treatment is needed, they do not need daily administered oral iron suppletion. Patients in the Ferinject-group need to stay a half day in the hospital. The possible disadvantages can be the side effects of Ferinject (see adverse Ferinject, Chapter 9 in the protocol).

Part 2:

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

All patients who underwent a gastric bypass and develop a irondeficiency postoperatively. (ferritin< 20microgram/l) Age between 18 and 65 years.

Exclusion criteria

iron deficiency preoperative, bloodtransfusios during studyperiod, ironcontaining nutritional supplements except the 'standard' multivitamins after bariatric surgery, decreased renal failure, excessive menstruational blood loss, anemia not caused by irondeficiency, accumulation of iron, hypersensitivity for one of the medicinal products, psychiatric illness, pregnancy

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2014
Enrollment:	240
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ferinject
Generic name:	Ferinject
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ferrous fumarate
Generic name:	Ferrous fumarate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ferrous gluconaat
Generic name:	Losferron
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-04-2014

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)

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	EUCTR2014-001444-37-NL
CCMO	NL48939.091.14