# Optimizing Iron suppletion trial after Roux- en -Y Gastric Bypass

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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.

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

## Summary

### ID

NL-OMON40886

**Source**
ToetsingOnline

**Brief title**
Ironsuppletion 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

## Intervention

**Keyword:** Iron, Suppletion

## Outcome measures

### Primary outcome

Serum ferritin, iron, hemoglobin, transferrin saturation, and transferrin after

6, 12 and 52 weeks after administration of ferrous fumarate, Losferron or

Ferinjet.

### Secondary outcome

Evaluate patients' preference of the route of administration : administered

orally (ferrous fumarate / Losferron) or intravenously (Ferinject).

# Study description

### Background summary

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 sprocedures can be divided in restrictive techniques, malabsorptieve techniques or a combination of both. The Adjustable Gastric Band (AGB) an the Gastric Sleeve (GS) are knows as restrictive technique, the Roux-en-Y gastric bypass (RYGB) is a combined technique with an average weight loss of 60-70 %. Unfortunately vitamin and mineral deficiencies are 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.

## Study objective

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.

## Study design

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).

## Study burden and risks

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 protocol).

## 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 developped an irondeficiency postoperatively (ferritin< 20 microfram/l) ,age between 18-65 years

## Exclusion criteria

iron deficiency preoperatve, bloodtransfusions during study period, ironcontaining nutritional supplements except the 'standard' multivitamins after bariatric surgery, decreased renal failure, excessive manstruational blood loss, anemia not caused by iron deficiency, accumulation of iron, hypersensitivity for one of the medicinal products, psychiatric illness, pregnancy.;Acute and chronic infection or other inflammationreactions, liver dysfunction.

# 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: | Pending |
| Start date (anticipated): | 01-08-2014 |
| Enrollment: | 120 |
| Type: | Anticipated |

## 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 gluconate |
| Generic name: | Losferron |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 16-06-2014 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 24-07-2014 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 19-02-2015 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 09-09-2015 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 05-11-2015 |
| 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 | EUCTR2014-002322-12-NL |
| CCMO | NL49631.091.14 |