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Effect of ferric carboxymaltose on phosphate homeostasis in patients with iron deficiency following bariatric surgery

Submission date
17/04/2018

Recruitment status
No longer recruiting

Registration date
09/05/2018

Overall study status
Completed

Last Edited
30/03/2020

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Iron deficiency leading to anemia is a frequent condition in patients following weight-loss surgery. Because of higher effectiveness and fewer side effects than oral supplements, iron is often given in the form of a short infusion in an outpatient setting. It is known that the iron infusion Ferinject can cause a fall in body phosphate through a mechanism not yet fully understood. A fall in phosphate often remains unnoticed, but can potentially lead to serious problems such as heart and respiratory insufficiency. Due to several reasons, patients after weight-loss surgery might be at higher risk for this condition. This study therefore aims to study the frequency and severity of a fall in phosphate one week after a Ferinject infusion as well as associated symptoms, duration and possible risk factors leading to its development in 50 patients following weight-loss surgery.

Who can participate?
Patients aged over 18 after weight-loss surgery who require iron infusion for iron deficiency

What does the study involve?
Patients are asked to join this study during their routine outpatient visit if their iron levels are below a certain range and they are prescribed a Ferinject infusion. Additional to the anyway planned Ferinject infusion, the patient is asked to provide a urine sample and a blood sample from the vein where the infusion is inserted. Ferinject is infused according to the manufacturer's instructions. Participants are asked to visit the Outpatient Clinic again after one week for another urine and blood sample and a questionnaire investigating possible symptoms of a fall in phosphate. If phosphate stays in normal range, no further visits are planned and study participation ends. If phosphate levels fall below normal range, the patient is asked to attend a further visit another week later for the same procedures. Participants are followed as long as their phosphate is below normal levels up to 12 weeks (to a maximum of 4 additional visits after the first visit). If a severe fall in phosphate occurs, the participant is advised to supplement phosphate (either orally or infused, according to severity).

What are the possible benefits and risks of participating?
There will be no immediate benefit to the participant. However, the results of the study can help to improve care of patients following weight-loss surgery. There will only be the small risk of a blood sample collection (rare: development of a bruise or pain at puncture site, very rare: local infection at of the puncture site).

Where is the study run from?
Kantonsspital St. Gallen (Switzerland)

When is the study starting and how long is it expected to run for?
November 2016 to May 2018

Who is funding the study?
Kantonsspital St. Gallen (Switzerland)

Who is the main contact?
Dr Stefan Bilz

Contact information

Type(s)
Scientific

Contact name
Dr Stefan Bilz

Contact details
Rorschacherstrasse 95
St. Gallen
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Additional identifiers

Protocol serial number
BASEC Nr. 2017-00271

Study information

Scientific Title
Effect of ferric carboxymaltose on phosphate homeostasis: a prospective cohort study in patients with iron deficiency following bariatric surgery

Study objectives
The trialists hypothesize that a significant portion of post-bariatric patients receiving parenteral FCM for the treatment of iron deficiency will develop significant hypophosphatemia secondary to enhanced renal losses through a mechanism involving the phosphatonin FGF23. This patient population is at increased risk to develop significant hypophosphatemia due to decreased oral intake, limited enteral resorption and secondary hyperparathyroidism as a predisposing state for hypophosphatemia caused by inadequate calcium intake or Vitamin D insufficiency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
EKOS: Ethikkommission Ostschweiz, 23/03/2017, BASEC Nr. 2017-00271

Study design
Single-center non-randomized non-interventional prospective clinical trial

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-bariatric surgery patients

Interventions
This is a single-center outpatient study with consecutive ongoing recruitment in the Obesity Clinic of the Cantonal hospital St. Gallen in routine consultations of patients after bariatric surgery. Investigators screen for and ask patients with a ferritin level ≤ 30 µg/l prescribed an outpatient infusion of ≥ 500mg FCM as part of routine medical care after bariatric surgery to participate the study.

Blood and urine samples are taken at baseline and at the end of week 1. If hypophosphatemia occurs at the end of week 1, patients are asked to attend another visit at the end of week 2 for the same procedures as at the end of week 1. If hypophosphatemia occurs at the end of week 2, patients are asked to attend another visit at the end of week 4. The same procedures will again be done according to if hypophosphatemia occurs at the previous visit at the end of week 8 and 12.

At each visit, laboratory parameters of phosphate homeostasis (blood and urine) will be measured and possible symptoms of hypophosphatemia will be assessed by a standardized questionnaire. According to the severity of hypophosphatemia, adequate substitution with oral or parenteral phosphate will be initiated.

Intervention Type
Other

Primary outcome(s)
Proportion of post-bariatric patients developing significant hypophosphatemia, defined as plasma phosphate levels < 0.8 mmol/l one week following the intravenous application of ferric carboxymaltose. Blood samples will be taken from an antecubital vein in a sitting position at Visit 0 (before administration of FCM) and at Visit 1 (one week after FCM). Blood tubes will be sent to central laboratory (ZLM, Cantonal Hospital St. Gallen) where plasma phosphate is measured by standard clinical methods.

Key secondary outcome(s))

1. Time to recovery from hypophosphatemia following parenteral therapy with FCM in post-bariatric patients, assessed by plasma phosphate levels from blood samples at V2-V5
2. Clinical symptoms associated with the development of hypophosphatemia following parenteral therapy with FCM in post-bariatric patients, assessed by a standardized interview and clinical exam at V0-V5
3. Risk factors leading to the development of hypophosphatemia following parenteral therapy with FCM in post-bariatric patients, assessed using baseline, demographic, clinical and laboratory parameters
4. Pathogenetic mechanisms associated with the development of hypophosphatemia, assessed using baseline demographic and clinical characteristics and parameters of phosphate homeostasis (serum intact and c-terminal FGF 23, PTH, 25 and 1,25 (OH)2 Vitamin D3)

Blood and urine markers of phosphate homeostasis and a standardized interview and clinical exam will be assessed at Visits 0-5. There is a minimum of one follow up visit (V1) one week after the screening visit (V0) and a maximum of 5 follow up visits until 12 weeks after screening visit. If the patient develops hypophosphatemia, discovered at visit 1 (V1), there will be a further visit. Each further visit after V1 will only be held if hypophosphatemia occurs at the previous visit.

Visit windows: visit 1 (V1, week 1) will occur within 7 ± 1 days after the screening visit, which is the visit when FCM is given intravenously. V2 will occur within 7 ± 2 days after V1. Visit 3 (V3, week 4) will occur within 14 ± 2 days after V2. From V3, visit 4 (V4, week 8) should occur within 4 weeks ± 3 days and from V4, visit 5 (V5, week 12) should again occur within 4 weeks ± 3 days.

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Age > 18 years
2. Previous bariatric surgery, i.e. Roux-Y-gastric bypass, gastric sleeve resection, biliopancreatic diversion
3. Planned parenteral intravenous iron therapy with ferric carboxymaltose according to local guidelines (serum ferritin < 15 mcg/l or < 30 mcg/l with a previous history of iron deficiency anemia or symptoms compatible with iron deficiency)
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Known hypersensitivity to FCM
2. Treatment with intravenous iron within the previous 14 days
3. Glomerular filtration rate < 60 ml/min/1.73m2 (CKD-EPI formula)
4. Plasma phosphate < 0.8 mmol/l at screening
5. Severe Vitamin D deficiency (< 20 nmol/l)
6. 1st trimester of pregnancy

Date of first enrolment
05/04/2017

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
Switzerland

Study participating centre
Klinik für Endokrinologie, Diabetologie, Osteologie und Stoffwechselerkrankungen, Kantonsspital St. Gallen
Rorschacherstrasse 95
9007 St Gallen
Switzerland
9007

Sponsor information

Organisation
Klinik für Endokrinologie, Diabetologie, Osteologie und Stoffwechselerkrankungen
Kantonsspital St. Gallen

ROR
https://ror.org/00gpmb873

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Division of Endocrinology and Diabetes, Kantonsspital St. Gallen

Results and Publications

Individual participant data (IPD) sharing plan
A full anonymised dataset supporting the findings of this study will be available from Dr Stefan Bilz upon reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2020	30/03/2020	Yes	No