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Evaluation of iron status in hemodialysis patients under maintenance therapy with intravenous iron

Submission date
15/12/2018

Recruitment status
No longer recruiting

Registration date
01/02/2019

Overall study status
Completed

Last Edited
22/08/2022

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Patients with renal failure being treated with hemodialysis usually suffer from anemia (a deficiency of red blood cells). Renal anemia is caused by several mechanisms, including repeated blood loss leading to iron deficiency as well as a functional iron deficiency caused by inflammation. Intravenous iron preparations are therefore given at regular intervals to most dialysis patients. The dose and interval of iron administrations is guided by laboratory parameters that reflect the body's iron stores. However, these laboratory parameters may be falsely elevated early after the administration of an iron dose and may not reflect true iron stores during this time period. The aim of this study is to measure these laboratory parameters repeatedly after an administered iron dose to evaluate how much time must elapse before these laboratory parameters can be used to evaluate total body iron stores in hemodialysis patients.

Who can participate?
Adult patients that require chronic hemodialysis treatment, are in an otherwise stable health status and receive intravenous iron in the form of ferrum carboxymaltose (an iron preparation) at a dose of 100 or 200mg every four weeks can participate.

What does the study involve?
The study involves blood sampling for assessment of iron parameters immediately before as well as on days 2, 4, 7, 14, 21 and 28 after an iron dose is being given. Blood samples are taken at the beginning of a hemodialysis session and do not require additional venipunctures. The iron administration schedule will not be modified for the study.

What are the possible benefits and risks of participating?
Participants will not directly benefit from the study since it does not involve a novel treatment. However, the knowledge gained through the study will facilitate treatment of renal anemia, which might also benefit the study participants. The risks of participating are minimal, because the study does not involve an active treatment or any interventions apart from the removal of

small blood volumes at the beginning of several hemodialysis treatments. Theoretically, the blood amount reduced might aggravate anemia, but this effect will be minimal because only small amounts of blood are collected.

Where is the study run from?
The study is conducted at two hemodialysis units (Kantonsspital Frauenfeld and Kantonsspital Münsterlingen) run by the same hospital (Spital Thurgau AG).

When is the study starting and how long is it expected to run for?
June 2017 to February 2018. The follow up time (i.e. the study duration for an individual study participant) is four weeks.

Who is funding the study?
The study is investigator-initiated and received an unrestricted funding by Vifor Pharma. Vifor Pharma has no influence in the study design or analysis.

Who is the main contact?
PD Dr. Andreas Kistler (Andreas.kistler@stgag.ch)

Contact information

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Public

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Additional identifiers

Protocol serial number
2017-00354

Study information

Scientific Title
Evaluation of iron stores In haemodialysis patients on maintenance ferrum carboxymaltose dosing

Acronym
N/A

Study objectives
Intravenous Ferrum Carboxymaltose leads to transient spurious rises of ferritin in hemodialysis patients, even if given at relatively low single doses of 100 or 200mg – and thus, the timing of blood sampling to evaluate the iron status in hemodialysis patients relative to the iron dosing schedule is relevant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of Eastern Switzerland (EKOS), 27/03/2017, ref. 2017-00354.

Study design
Prospective, observational

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End stage kidney disease on dialysis

Interventions
Patients taking part in this trial attend their normal dialysis schedule. At the beginning of the dialysis session before patients receive their regularly scheduled iron dose, blood is drawn to assess the iron stores (ferritin and transferrin saturation) as well as other hematological and inflammatory parameters through the needle inserted into the dialysis fistula or via the dialysis catheter if applicable. Blood samplings are repeated at the initiation of scheduled hemodialysis treatments on days 2,4,7,14,21 and 28 after FCM administration. The total duration for every patient is 28 days.

Intervention Type
Other

Primary outcome(s)
1. Change of serum ferritin from baseline to peak value. Serum ferritin is measured using an electrochemiluminescence method at baseline and at days 2,4,7,14,21 and 28. The values are compared using a two-sided paired t-test.
2. Change of transferrin saturation from baseline to peak value. Transferrin saturation (TSAT) is

calculated from the serum iron and serum transferrin. Serum iron are measured using a spectrometry and serum transferrin is measured using an immunological agglutination assay at baseline and at days 2,4,7,14,21 and 28. The values are compared using a two-sided paired t-test.

Key secondary outcome(s))
1. Time to normalisation of ferritin and transferrin saturation (TSAT) values are calculated by comparing the ferritin and TSAT values of every time point assessed to the respective baseline values. Time to normalisation of ferritin and transferrin saturation (TSAT) values are defined as
1.1. The time when the mean values are no longer different from baseline
1.2. When ferritin and TSAT values are <100 µg/l and <10% above baseline, respectively, in >75% of patients.
2. Change of ferritin and TSAT for every time point assessed is calculated and compared using a two-sided paired t-test.
3. Changes in other laboratory parameters are calculated and compared to their baseline values using a two-sided paired t-test for every time point.

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Chronic hemodialysis patients receiving either 100 or 200 mg FCM every 4 weeks.
2. Age 18 years or older
3. HD treatment for at least three months
4. Thrice-weekly hemodialysis
5. Stable FCM dosing schedule for the last two months or longer
6. Stable erythropoietin stimulating agents (ESAs) for patients receiving ESAs (defined by dose adjustments of <25% within the last two months)
7. Haemoglobin values between 95g/l and 125g/l within the last 12 weeks with a difference between the lowest and the highest value of <15g/l.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
39

Key exclusion criteria
1. Clinical evidence of significant blood loss within the last 12 weeks (e.g. gastrointestinal bleeding)
2. Significant inflammation (CRP >15 mg/l)
3. Hospital admission within the last month
4. Significant bacterial infection (e.g. pneumonia) within the last 12 weeks.

Date of first enrolment
01/01/2017

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
Switzerland

Study participating centre
Cantonal hospital of Frauenfeld
Pfaffenholzstrasse 4
Frauenfeld
Switzerland
8501

Sponsor information

Organisation
Dr. med. A. Kistler

Funder(s)

Funder type
Industry

Funder Name
Vifor Pharma

Alternative Name(s)
Vifor Pharma Management Ltd., Vifor Pharma Management AG, Vifor Pharma Management SA, Vifor Pharma Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the corresponding author (Andreas D. Kistler; andreas.kistler@stgag.ch). Source data are stored in the electronic health records of the hospital, including a fully electronic reporting of laboratory data. Outcome parameters and baseline parameters used are entered anonymized into a data file, which is stored on the hospital servers. Data generation, transmission, storage and analysis of health related personal data and the storage of biological samples within this project follow strictly the current Swiss legal requirements for data protection. Consent from all participants has been obtained. The dataset as well as all other study related materials (informed consent forms, study protocol) will be stored for at least 10 years after the termination of the study. Biological samples will be destroyed 2 years after termination of the study. The destruction of the samples will be documented in the investigator file. After completion of the study and publication of results, data will be shared in fully anonymized form with interested researchers on request, provided that their research question is not currently already being analyzed by the study investigators.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	10/03/2020	Yes	No
Basic results		19/02/2019		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	24/02/2017	22/08/2022	No	No