

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

Submission date 15/12/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/08/2022	Condition category Urological and Genital Diseases	<input type="checkbox"/> 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

Type(s)

Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request at participant information sheet.

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 measure

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.

Secondary outcome measures

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 $<100 \mu\text{g/l}$ 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.

Overall study start date

01/03/2016

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 $<15\text{g/l}$.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

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

Sponsor details

Pfaffenholzstrasse 4
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8501

Sponsor type

Other

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**Publication and dissemination plan**

The results of the study will be submitted for presentation at the annual meetings of the Swiss Society of Nephrology (SSN), the American Society of Nephrology (ASN) and the European Renal Association – European Dialysis and Transplantation Association (ERA-EDTA). The study will be submitted for publication in a peer reviewed journal.

Intention to publish date

01/06/2018

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?
Basic results		19/02/2019		No	No
Results article	results	01/03/2019	10/03/2020	Yes	No
Protocol file	version 1.0	24/02/2017	22/08/2022	No	No