

Comparative study of safety and efficacy of ferric carboxymaltose and iron sucrose in women

Submission date 12/12/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 15/12/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/01/2019	Condition category Haematological Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Iron deficiency anaemia (IDA) is a condition where a lack of iron in the body leads to a reduction in the number of red blood cells. The aim of this study is to assess the effectiveness and safety of intravenous ferric carboxymaltose (FCM) in comparison to iron sucrose (IS) in women with IDA.

Who can participate?

Women over the age of 18 with IDA

What does the study involve?

Participants are randomly allocated to receive either FCM or IS. The study lasts for six months. Participants undergo assessments at the start of the study and at weeks 2 and 4. The goals are to find out whether it is possible to achieve target levels in laboratory tests; to identify and prevent any possible drug-related problems in patients on FCM or IS; to make suggestions for the use of these drugs whenever required by evaluating the laboratory tests; to assess the time required to attain normal laboratory tests using these two drugs; and to evaluate health-related quality of life using questionnaires.

What are the possible benefits and risks of participating?

Patients receive treatment for IDA. The study's findings should help in choosing a drug treatment for IDA in women. The main risk is an adverse drug reaction to intravenous iron.

Where is the study run from?

The study is run by the University of Kashmir and takes place in Sher-i-Kashmir Institute of Medical Sciences (SKIMS) Medical College and Hospital, Bemina, Srinagar (India)

When is the study starting and how long is it expected to run for?

May 2015 to February 2016

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Additional identifiers

Protocol serial number

SKIMS MC/CM/IEC/15/42-50

Study information

Scientific Title

Effectiveness and safety of ferric carboxymaltose compared to iron sucrose in women with iron deficiency anemia: Phase IV clinical trials

Study objectives

To check which of the two Iron preparations, ferric carboxymaltose or iron sucrose, is better in the treatment of iron deficiency anemia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Ethics Committee, Sheri-Kashmir Institute of Medical Sciences Medical College and Hospital (IEC-SKIMS MCH), 16/07/2015, ref: SKIMS MC/CM/IEC/15/42-50

Primary study design

Interventional

Study design

Prospective longitudinal and interventional study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Treatment of iron deficiency anemia in women with different comorbidities

Interventions

Female patients were enrolled for the study and a well-informed written consent was taken from all the patients before starting the therapy. Participants were randomly allocated in a 1:1 ratio using SNOSE to receive either ferric carboxymaltose or iron sucrose.

In conformity with the standard indicators, ferric carboxymaltose and iron sucrose was given in women with iron deficiency anemia after properly evaluating the baseline demographic and clinical characteristics of the study patients. Hospital doctors and the pharmacologist were involved in choosing a dose, maintenance of the therapy and monitoring of the adverse drug reactions (ADRs). While as the administration of the drug was done by nursing staff. According to the Ganzoni's Formula total iron required for iron repletion was calculated at baseline. The intravenous iron infusion was given according to the iron deficit calculated by and rounded up to the nearest multiple of 100 for each individual. The maximum dose of iron sucrose was 200 mg diluted in 200 ml of sterile normal saline 0.9% and given as a slow infusion over 30 minutes. The rest of the doses, as and when required, were given on alternate days following the same procedure. The maximum single dose of FCM was 1,000 mg diluted in 250 ml of sterile normal

saline 0.9% given as a slow infusion over 45 minutes. If needed, rest of the doses were given on the 8th and the 15th day. In case of any adverse drug reaction (ADR), the infusion was stopped, documented, and the patient was treated for the respective ADR.

The study lasted for six months. Participants also asked to complete HRQOL questionnaires and assessments at week 2 and 4.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Iron sucrose, ferric carboxymaltose

Primary outcome(s)

Measured at baseline, 2 and 4 weeks:

1. The effectiveness and safety of FCM with respect to IS in achieving the target levels of laboratory biomarkers such as Hb, mean corpuscular volume (MCV), serum iron (SI), serum ferritin (SF), transferrin saturation (TS%), total iron binding capacity (TIBC) levels as prescribed under standard guidelines
2. Drug-related problems in patients on FCM or IS
3. The time required to attain normal laboratory biomarker levels

Key secondary outcome(s)

Health-related quality of life (HRQOL), measured using the Medical Outcomes Study Short Form 36 (SF-36) at baseline, 2 and 4 weeks

Completion date

25/02/2016

Eligibility

Key inclusion criteria

All patients diagnosed with IDA admitted/or present for consultation in the Obstetrics and Gynecology ward of SKIMS Medical College and Hospital, Bemina, Srinagar were enrolled during the study period

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

Female

Key exclusion criteria

1. Patients with uncontrolled hypertension
2. Patients with impaired renal function
3. Patients with impaired liver function
4. Patients with heart disease

Date of first enrolment

20/07/2015

Date of final enrolment

13/02/2016

Locations**Countries of recruitment**

India

Study participating centre

Sher-i-Kashmir Institute of Medical Sciences Medical College and Hospital

Department of Obstetrics and Gynaecology

Bemina

Srinagar

India

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Sponsor information**Organisation**

University of Kashmir

ROR

<https://ror.org/032xfst36>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as they contain personal information related to the patient that needs to be kept confidential.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/01/2018		Yes	No