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

Submission date
12/12/2017

Recruitment status
No longer recruiting

Registration date
15/12/2017

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
1. Dr Ghulam N Bader
gnbader@kashmiruniversity.ac.in
2. Amreen Naqash
anaqash.scholar@kashmiruniversity.net

Contact information

Type(s)
Scientific

Contact name
Dr Ghulam Bader

Contact details
Department of Pharmaceutical Sciences
University of Kashmir
Srinagar
India
190006
+91 (0)9419055344
gnbader@kashmiruniversity.ac.in

Type(s)
Scientific

Contact name
Prof Rifat Ara

Contact details
Department of Obstetrics and Gynecology
SKIMS Medical College and Hospital
Srinagar
India
190017

Type(s)
Scientific

Contact name
Miss Amreen Naqash

Contact details
Department of Pharmaceutical Sciences
University of Kashmir
Srinagar
India
190006
+91 (0)7889776179
anaqash.scholar@kashmiruniversity.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective longitudinal and interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

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

Overall study start date
01/05/2015

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

Age group
Mixed

Sex
Female

Target number of participants
200

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
190017

Sponsor information

Organisation
University of Kashmir

Sponsor details
Department of Pharmaceutical Sciences
University of Kashmir
Hazratbal
Srinagar
India
190006

Sponsor type
University/education

Website
http://pharma.uok.edu.in/Main/Default.aspx

ROR
https://ror.org/032xfst36

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The work has been accepted for publication in BMC Women's Health.

Intention to publish date
20/12/2017

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 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