

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

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| <b>Submission date</b><br>12/12/2017   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>15/12/2017 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>29/01/2019       | <b>Condition category</b><br>Haematological Disorders | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> 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

## 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

## Study design

Prospective longitudinal and interventional study

## Primary study design

Interventional

## 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

190017

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 05/01/2018   |            | Yes            | No              |