Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy and Safety Study of Injection Iron Sucrose in Pregnant Women with Iron Deficiency Anaemia

Protocol summary

Summary
Objective: To evaluate safety and efficacy of Test Product; Megafer Injection® in Prergnant women with iron deficiency Anemia. Inclusion Criteria: Pregnant Women in second or third trimester of pregnancy, Hb: ≤ 8 g/dl and serum ferritin levels are below than normal Exclusion Criteria: Patient allergic to iron preparation or any other ingredient of Injection megafer . Study Population: Pregnant Women Sample Size: 50 subjects Intervention: Megafer Injection® (Iron Sucrose 100mg/5ml), Main Outcomes measures: Increase in Hb level at 2-4 weeks after initiation of treatment, achievement of target haemoglobin.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201611037978N4**
Registration date: **2016-11-18, 1395/08/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2016-11-18, 1395/08/28

Registrant information

Name
Tasneem Ahmad
Name of organization / entity
Pharma Professional Services, Karachi, Pakistan
Country
Pakistan
Phone
(92-21) 34972358, 34820573
Email address
tasneem.ahmed@iccs.edu

Recruitment status
Recruitment complete

Funding source
Surge Laboratories (Private) Ltd.

Expected recruitment start date
2015-07-31, 1394/05/09
Expected recruitment end date
2016-01-18, 1394/10/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy and Safety Study of Injection Iron Sucrose in Pregnant Women with Iron Deficiency Anaemia

Public title
Efficacy and Safety Study of Megafer injection® in Pregnant Women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Pregnant Women in second or third trimester, Hb: ≤ 8 g/dl and serum ferritin levels are below than normal Exclusion Criteria: Patient allergic to iron preparation or any other ingredient of Injection megafer.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Single arm, Open label study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Jinnah Post Graduate Medical Centre
Street address
Rafiqui Shaheed Road, Jinnah Post Graduate Medical Centre
City
karachi
Postal code
75510
Approval date
2015-02-14, 1393/11/25
Ethics committee reference number
NO.F.2-81/2015-GENL/11128/JPMC

Health conditions studied

1

Description of health condition studied
Iron Deficiency anemia
ICD-10 code
D-50
ICD-10 code description
Iron Deficiency anemia, unspecified

Primary outcomes

1

Description
Increase in Hb level after initiation of treatment, achievement of target haemoglobin.
Timepoint
2 & 4 weeks after first dose
Method of measurement
Haemoglobin testing

Secondary outcomes

1

Description
Reported adverse events related to drug only.
Timepoint
At every follow up visit
Method of measurement
Patient monitoring & Follow up calls to patients

Intervention groups

1

Description
The total calculated dose was divided as 100 to 200 mg dose/day maximum once or twice in week. Firstly, 25mg (25ml) was infused over 30 minutes @12 drops /minute as a test dose and the remaining dose was given at the rate 30-36 drops /minute, aiming the target haemoglobin of 11g/dl.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Jinnah Postgraduate Medical Centre (JPMC)
Full name of responsible person
Dr. Haleema Yasmeen
Street address
Department of Gynecology, Jinnah Postgraduate Medical Centre (JPMC)
City
karachi

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Surge Laboratories Pvt. Ltd.
Full name of responsible person
Mohammad Younus Batla
Street address
509-510, 5th Floor, Commerce Centre, Hasrat Mohani Road, Karachi, Pakistan
City
Karachi
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Surge Laboratories Pvt. Ltd.

Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Nabiqasim Industries (Pvt) Ltd.
Full name of responsible person
Salman Rahim
Position
Assistant Manager Regulatory Affairs.
Other areas of specialty/work
Street address
510, 5th floor, commerce center, Hasrat Mohani Road
City
Karachi
Province
Sindh
Postal code
74200
Phone
0092213263631
Fax
Email
salman.rahim@nabiqasim.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Gynaecology, Jinnah Post Graduate Medical Centre
Full name of responsible person
Dr. Haleema Yasmeen
Position
Assistant Professor
Other areas of specialty/work
Street address
Rafiqui Shaheed Road, Jinnah Post Graduate Medical Centre
City
karachi
Province
Sindh
Postal code
75510
Phone
00922199201300
Fax
Email
dr.haleemayasmin@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Pharma Professional Services
Full name of responsible person
Prof.Dr. Tasneem Ahmad
Position
Chief Investigator
Other areas of specialty/work
Street address
A-93, Ettawah Society, scheme 33
City
karachi
Province
Sindh
Postal code
75340
Phone
00
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty