

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Pregnant women with iron deficiency Anemia. Inclusion Criteria: Pregnant Women in second or third trimester of pregnancy, Hb: \leq 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: \leq 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

Rafiqi 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***City**

karachi

Province

Sindh

Postal code

75510

Phone

00922199201300

Fax**Email**

dr.haleemayasmin@yahoo.com

Web page address**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 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****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**

Rafiqi Shaheed Road, Jinnah Post Graduate Medical Centre

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*