

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 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*