

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy and Safety Study of Fixed Dose Combination Tablet of Iron Polymaltose and Folic Acid (Tablet Irpo- FA®) in Pregnant Women with Iron Deficiency Anaemia.

Protocol summary

Summary

Objective: To evaluate safety and effectiveness of Test Product; irpo-FA Tablets in Pregnant women with iron deficiency Anemia. Inclusion Criteria: Pregnant Women in second or third trimester or after 12 weeks of pregnancy, Hb: ≤ 10 . 5g/dl after first trimester and serum ferritin levels are below than normal (less than 35 $\mu\text{g/l}$) Exclusion Criteria: Patient with a history of non-compliance with iron therapy or allergic to iron preparation. Study Population: Pregnant Women Sample Size: 50 subjects Intervention: Irpo-Fa ® Iron(III)Hydroxide Polymaltose 100mg; Elemental Iron Folic Acid 0.5 mg, Main Outcomes measures: Increase in Hb level at 2 weeks, 1 month, 2 months and three months after initiation of oral iron therapy, Correction in anaemia within or on completion of three months of treatment.

General information

Acronym

None

IRCT registration information

IRCT registration number: **IRCT201610197978N3**

Registration date: **2016-10-31, 1395/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-31, 1395/08/10

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

Pharmaceutical Company

Expected recruitment start date

2015-04-15, 1394/01/26

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 Fixed Dose Combination Tablet of Iron Polymaltose and Folic Acid (Tablet Irpo- FA®) in Pregnant Women with Iron Deficiency Anaemia.

Public title

Efficacy and Safety Study Tablet (Irpo- FA®) in Pregnant Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Pregnant Women in second or third trimester or after 12 weeks of pregnancy, Hb: ≤ 10 . 5g/dl after first trimester and serum ferritin levels are below than normal (less than 35 $\mu\text{g/l}$) Exclusion Criteria: Patient with a history of non-compliance with iron therapy or allergic to iron preparation.

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 & Folic acid Deficiency anemia

ICD-10 code

D-50 & D-5

ICD-10 code description

Iron deficiency anaemia, unspecified & Folate deficiency anaemia, unspecified

Primary outcomes

1

Description

Increase of 1g/dl Hb with 100-200mg/day elemental iron

Timepoint

2 weeks, 1 month, 2 months and three months after initiation of oral iron therapy

Method of measurement

C. B. C, Ferritin, iron profile tests

Secondary outcomes

1

Description

Gastrointestinal adverse events

Timepoint

At every visit and Follow up checkups

Method of measurement

Patient monitoring & Follow up calls to patients

Intervention groups

1

Description

Each patient received irpo-FA (combination tablet of Iron Polymaltose (100mg elemental iron) & 0.35 mg folic acid oral tablets O. D, following the instructions as chew the tablets on empty stomach, 1 hour before or after meal for 3 months as prescribed by the doctor.

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

Nabiqasim Industries (Pvt) Ltd.

Full name of responsible person

Mohammad Younus Batla

Street address

510, 5th floor, commerce center, Hasrat Mohani Road

City

Karachi.

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nabiqasim Industries (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

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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

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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

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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