Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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 Prergnant women with irondeficiency 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 µg/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 µg/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
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 & 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

Street address

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

City

karachi

Province

Sindh

Postal code

74200

Phone

009221 32636313

Fax

Email

salman.rahim@nabiqasim.com

Web page address

www.nabiqasim.com

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

92-21-99201300

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

75343

Phone

00922136352328

Fax

Email

dr.tasneem@phaps.com

Web page address

www.phaps.com

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