

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study for the safety and effectiveness of a commercial product of 2 mg dinoprostone vaginal gel in pregnant women.

Protocol summary

Summary

Objective of the study: to evaluate the safety and effectiveness of 2mg dinoprostone vaginal gel when used in real life for the induction of labor in pregnant women. Inclusion Criteria: All pregnant women age above 18 years; scheduled for induction of labor with 2mg dinoprostone vaginal gel; bishop less than or equal to 4. Exclusion criteria: Bishop greater than 4. Study population: pregnant women. Sample size: 45 subjects. Intervention: Dinoprostone 2mg vaginal gel. Main outcomes measures: bishop score & mode of delivery were recorded to evaluate the treatment success. Secondary outcomes includes maternal, fetal and neonatal adverse events.

General information

Acronym

None

IRCT registration information

IRCT registration number: **IRCT201502187974N6**

Registration date: **2015-03-14, 1393/12/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-14, 1393/12/23

Registrant information

Name

Ghousia Saba

Name of organization / entity

Pharma Professional Services

Country

Pakistan

Phone

(92-21) 36352328

Email address

ghousia@phaps.com

Recruitment status

Recruitment complete

Funding source

Pharmaceutical Company

Expected recruitment start date

2014-08-26, 1393/06/04

Expected recruitment end date

2014-10-10, 1393/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study for the safety and effectiveness of a commercial product of 2 mg dinoprostone vaginal gel in pregnant women.

Public title

Safety and effectiveness of dinoprostone vaginal gel in pregnant women.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Pregnant women; scheduled for labor induction with 2mg Dinoprostone vaginal gel; bishop score less than or equal to 4. Exclusion criteria: Bishop score greater than 4.

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: 45

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

1

Registry name

WHO

Secondary trial Id

U1111-1167-6462

Registration date

2015-02-25, 1393/12/06

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of services institute of medical sciences

Street address

Ghus-ul-azam (jail road), services institute of medical sciences, services hospital

City

Lahore

Postal code

Approval date

2014-07-16, 1393/04/25

Ethics committee reference number

IRB/2014/80/SIMS

Health conditions studied

1

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

XV

ICD-10 code description

The codes included in this chapter are to be used for conditions related to or aggravated by the pregnancy, childbirth or by the puerperium (maternal causes or obstetric causes)

Primary outcomes

1

Description

increase of 3 in bishop score

Timepoint

six hours and 12 hours after dosing

Method of measurement

Bishop scoring method

2

Description

Attainment of bishop score of 6 or more

Timepoint

six and 12 hours after dosing

Method of measurement

Bishop scoring method

3

Description

vaginal delivery occurring within 12 hours of dosing

Timepoint

occurring within 12 hours of dosing

Method of measurement

subject monitoring

Secondary outcomes

1

Description

Maternal adverse events

Timepoint

from dosing to delivery

Method of measurement

Patient monitoring

2

Description

Neonatal adverse events

Timepoint

just after birth at 1 & 5 minutes

Method of measurement

APGAR score

3

Description

Fetal Adverse events

Timepoint

two hours after dosing, at six & 12 hours after dosing (till baby is not delivered)

Method of measurement

by measuring CTG

Intervention groups

1

Description

Dinoprostone 2mg vaginal gel (Glandin E2) inserted high into posterior fornix. dose repeated (if required and prescribed by doctor) after six hours of first dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Services hospital

Full name of responsible person

Prof. Dr. Rubina Sohail

Street address

Ghus-ul-azam (Jail road),

City

Lahore

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nabiqasim Industries (Pvt) Ltd.

Full name of responsible person

Salman Rahim

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Services Hospiatl

Full name of responsible person

Prof. Dr. Rubina Sohail

Position

Professor Gynae unit II

Other areas of specialty/work

Street address

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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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Karachi

Province

Sindh

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75343

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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