Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 then or equal to 4. Exclusion criteria: Bishop greater then 4. Study population: pregnant women. Sample size: 45 subjects. Intervation: 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 then 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
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
Services Hospiatl
Full name of responsible person
Prof. Dr. Rubina Sohail
Position
Professor Gynae unit II
Other areas of specialty/work
Street address
Ghus-ul-azam (jail road)
City
Lahore
Province
Punjab
Postal code
Phone
009242
Fax
Email
rubina95@gmail.com
Web page address
www.sims.edu.pk

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