

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

In vivo performance of two commercial products of dinoprostone vaginal tablets and safety study of phosphate enema in pregnant women.

Protocol summary

Summary

Objective: The objective of the study is to establish the bioequivalence of a commercial product of Dinoprostone 3mg vaginal tablet against reference product and to establish the safety of Kleen enema while use in pregnancy before induction. Inclusion Criteria: pregnant women at or near term gestation (≥ 37 weeks) with a medical or obstetrical indication for the induction of labor; Age: 18-35 years; singleton pregnancy with cephalic presentation; parity ≤ 3 ; intact membrane; bishop score less than or equal to 4; fetal reactive non-stress test. Exclusion Criteria: neuropathy; renal impairment; liver disease; diabetes; hypertension & CV disease; placenta previa; placental abruption; vasa previa; active herpes genitalia; spontaneous labour; fetal death in-utero; where oxytocic drugs are contraindicated or where prolong contractions of uterus are considered inappropriate. Kleen enema will not be administered if subject is with diarrhoea & vomiting. Study population: pregnant women with an indication for induction of labor at term pregnancy. Sample Size: total 90 subjects & PP-population is minimum 70. Intervention: test product "A" is Dinoprostone 3mg vaginal tablet manufactured by Nabiqasim Industries (Pvt) Ltd; Reference product "B" Dinoprostone 3mg vaginal tablet (Prostin-E2) ; Test product "C" is Kleen enema manufactured by Nabiqasim Industries (Pvt) Ltd. Primary outcomes: An increase of 3 in bishop score; attainment of bishop score of 6 or more; or vaginal delivery occurring within 12 hours of dosing was considered as treatment success.; number & nature of adverse events occurring after kleen enema dosing but before induction with dinoprostone. Secondary outcomes: maternal, fetal and neonatal adverse events.

General information

Acronym

DINO (V.T) BE003

IRCT registration information

IRCT registration number: **IRCT201503037974N7**

Registration date: **2015-06-28, 1394/04/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-28, 1394/04/07

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

2014-03-20, 1392/12/29

Expected recruitment end date

2014-06-30, 1393/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo performance of two commercial products of dinoprostone vaginal tablets and safety study of phosphate enema in pregnant women.

Public title

In vivo performance of two commercial products of dinoprostone vaginal tablet and safety study of Kleen enema.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: pregnant women at or near term gestation (≥ 37 weeks) with a medical or obstetrical indication for the induction of labor; Age: 18-35 years; singleton pregnancy with cephalic presentation; parity ≤ 3 ; intact membrane; bishop score less than or equal to 4; fetal reactive non-stress test. Exclusion criteria: neuropathy; renal impairment; liver disease; diabetes; hypertension & CV disease; placenta previa; placental abruption; vasa previa; active herpes genitalia; spontaneous labour; fetal death in-utero; where oxytocic drugs are contraindicated or where prolong contractions of uterus are considered inappropriate. Kleen enema will not be administered if subject is with diarrhoea & vomiting.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

this is a single blind, two arm, parallel, randomized control study for dinoprostone. While for Kleen enema it is a single arm non-randomize study.

Secondary Ids

1

Registry name

WHO

Secondary trial Id

U1111-1167-6717

Registration date

2017-02-26, 1395/12/08

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jinnah Postgraduate Medical Center

Street address

Jinnah Postgraduate Medical Center, Rafique Shaheed Road

City

Karachi

Postal code

75510

Approval date

2014-02-15, 1392/11/26

Ethics committee reference number

2-81/2014-GENL/23711/JPMC

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

Cervical dilatation i.e. an increase of 3 in bishop from baseline

Timepoint

At six hours and 12 hours after dosing

Method of measurement

Bishop scoring

2

Description

Cervical dilatation i.e. Attainment of bishop score of 6 or more

Timepoint

At six hours and 12 hours after dosing

Method of measurement

Bishop scoring

3

Description

Vaginal delivery

Timepoint

Vaginal delivery occurring within 12 hours of dinoprostone dosing

Method of measurement

through Observation

4

Description

Kleen enema Adverse events

Timepoint

within half an hour after Kleen Enema dosing (before Dinoprostone Vaginal dosing)

Method of measurement

Adverse event monitoring by subject monitoring

Secondary outcomes

1

Description

Maternal adverse events

Timepoint

after dosing till delivery for dinoprostone. and after phosphate enema dosing till before the dosing of dinoprostone.

Method of measurement

through adverse event monitoring

2

Description

Fetal Adverse events

Timepoint

After Dinoprostone vaginal tablet dosing till delivery

Method of measurement

CTG & obstetrical examination

3

Description

Neonatal adverse events

Timepoint

Just after birth at 1 & 5 minutes

Method of measurement

APGAR score

Intervention groups

1

Description

Dinoprostone 3mg vaginal tablet (Test Product: Glandin E2). a dose of 3mg vaginal tablet was inserted high into posterior fornix a second dose was given in some patients (if required & prescribed by doctor) after six hours. And a single dose of Kleen Enema 120 ml was given rectally before dinoprostone doing.

Category

Treatment - Drugs

2

Description

Dinoprostone 3mg vaginal tablet (Reference Product: Prostin E2). a dose of 3mg vaginal tablet was inserted high into posterior fornix a second dose was given in some patients (if required & prescribed by doctor) after six hours. And a single dose of Kleen Enema 120 ml was

given rectally before dinoprostone doing.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Gynae and obstt at Jinnah postgraduate medical center

Full name of responsible person

Dr. Haleema Yasmin

Street address

Jinnah Postgraduate Medical Centre (JPMC), Rafiqui Shaheed Road

City

Karachi

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nabiqasim Industries (Pvt) Ltd.

Full name of responsible person

Mr. Salman A. 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

Mr. Salman A. Rahim

Position

Assistant Manager Regulatory Affairs

Other areas of specialty/work

Street address

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Province

Sindh

Postal code

74200

Phone

00922132636919

Fax**Email**

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Web page address

www.nabiqasim.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Department of Gynae and obstt at Jinnah postgraduate medical center

Full name of responsible person

Dr. Haleema Yasmin

Position

Assistant Professor

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**Street address**

A-93, Ettawah Society, scheme 33

City

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Postal code

75343

Phone

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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