Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Oct 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
Inclussion 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

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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
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Person responsible for updating data

Contact
Name of organization / entity
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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