Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of vaginal PH on efficacy of controlled- release Dinoprostone vaginal insert for cervical ripening/ labor induction.

Protocol summary

Summary

Prostaglandins are effective for ripening of cervix and induction of labor. Probably vaginal PH is an important factor in the effectiveness of vaginal prostaglandins. The aim of this study was to evaluate the effect of vaginal PH on the function of prostaglandin vaginal tablet in labor course. This was a clinical trial study on 147 pregnant primigravid women in age range of 16-35 years. Initial PH was measured during vaginal examination with Nitrazin paper and the Bishop score determined. All women received vaginal Dinoprostone inserted in posterior fornix of vagina for cervical ripening and the second dose was administered if the uterine contractions were inadequate. The reassessment of Bishop Score after 12 hours, duration of latent and active phase and also the duration of the second stage of labor was compared between two groups of the study (high or low vaginal PH).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904091760N7**
Registration date: **2010-06-30, 1389/04/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-06-30, 1389/04/09

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 2282

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2005-10-20, 1384/07/28

Expected recruitment end date

2006-10-20, 1385/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vaginal PH on efficacy of controlled- release Dinoprostone vaginal insert for cervical ripening/ labor induction.

Public title

Effect of vaginal PH on efficacy of controlled- release Dinoprostone vaginal insert for cervical ripening/ labor induction.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with age 16-35 years, nulligravida, single tone pregnancy, cephalic presentation, Bishop Score equal or less than 5, no contraindication for vaginal delivery, uterine contractions did not start. Exclusion criteria: known allergy to

prostaglandins, membrane rupture, fetal infection, history of previous surgery on the uterus and the previous induction of labor in recent pregnancy.

Age
From **16 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **147**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethics committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Gangafroz Avenue

City
Babol

Postal code
4717641367

Approval date
2005-10-12, 1384/07/20

Ethics committee reference number
1015

Health conditions studied

1

Description of health condition studied
Labor Induction

ICD-10 code
O00-O99

ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
cervix softening

Timepoint
After 12 hours of placing a vaginal suppository

Method of measurement
Bishop score

Secondary outcomes

1

Description
Duration of the stages of labor

Timepoint
Intervals between each stage (Latent phase, the active phase and second stage of labor)

Method of measurement
From time to start feeling regular contractions to dilatation 3-5 cm (Latent phase) / Dilatation from 3-5 cm to complete dilatation (active phase) / Since the complete withdrawal dilatation to fetus (Second stage of labor)

Intervention groups

1

Description
Vaginal tablets Dinoprostone (Containing 3 mg)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yahyanejad Hospital

Full name of responsible person
Dr. Azita Ghanbarpoor Shiadeh

Street address
Yahyanejad Hospital

City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person
Dr. Ali Bijani

Street address

Gangafroz Avenue

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

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

Fatemehzahra Fertility & Reproductive Health Reseach Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

M.A/Responsible of Reseach Center

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Fatemehzahra Fertility & Reproductive Health Reseach Center

Full name of responsible person

Dr. Zahra Basirat

Position

Gynecologist

Other areas of specialty/work

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Email

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Web page address

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