

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Email address

zahra@mubabol.ac.ir

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

Street address

Fatemehzahra Fertility & Reproductive Health Reseach Center, Noshirvani street

City

Babol

Postal code

4719173716

Phone

+98 11 1227 4881

Fax

+98 11 1227 4880

Email

ngh_pa@yahoo.com , zahra@mubabol.ac.ir

Web page address

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

Street address

Fatemehzahra Fertility & Reproductive Health Reseach Center, Noshirvani street

City

Babol

Postal code

4719173716

Phone

+98 11 1227 4881

Fax

+98 11 1227 4880

Email

zahra_basirat@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Fatemehzahra Infertility & Reproductive Health Research Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

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+98 11 1227 4881

Fax

+98 11 1227 4880

Email

ngh_pa@yahoo.com

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