

# 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

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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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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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**Full name of responsible person**

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**Position**

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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*