

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of Prostaglandine E2 and intra-cervical Foley balloon in labor induction

#### Protocol summary

##### Summary

Prostaglandine E2 and intra-cervical catheter are categories of cervical ripening before induction of labor. The aim of this study is to compare the effect of the intra-cervical Foley catheter and Prostaglandine E2 vaginal tablet in preinduction cervical ripening. In this study, 89 women with inclusion criteria (term and first pregnancy with Bishop Score less than 5 that had indication for vaginal delivery ,...) and exclusion criteria (PROM, ...) entered the study. Patients were randomized into two groups and they matched by maternal age. In first group: A 3mg Prostaglandin E2 vaginal tablet was put in posterior Culdusac; then primary and new bishop score noted after 12 hours and induction with Oxytocin started after 12 hours (if needed). In second group: An intra-cervical Foley catheter (size of 16) was put intra-cervix with sterile condition and it fixed by 15 mlit liquid; then primary and new bishop score noted after 12 hours and induction with Oxytocin started (if it needed). Solution of Oxytocin was 10 IU in 1 lit serum (Ringer) that at first started with 6MIU per min and every 20 min added to eight drops of up to 64 drops can be increased. Changes of Bishop Score, type of delivery, use of Oxytocin, infant status and possible complication recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012071760N10**

Registration date: **2011-02-02, 1389/11/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-02-02, 1389/11/13

#### 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

2007-05-22, 1386/03/01

#### Expected recruitment end date

2008-05-21, 1387/03/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Efficacy of Prostaglandine E2 and intra-cervical Foley balloon in labor induction

#### Public title

Efficacy of Prostaglandine E2 and intra-cervical Foley balloon in labor induction

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: Term pregnant women (37-42 weeks),

first pregnancy that had indication of labor and Bishop Score less than 5. Exclusion criteria: Rupture of membrane, Twin pregnancy, Preterm labor and closed cervix.

**Age**

No age limit

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **89**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical sciences

**Street address**

Gangafroz Avenue

**City**

Babol

**Postal code****Approval date**

2007-04-28, 1386/02/08

**Ethics committee reference number**

6725

**Health conditions studied****1****Description of health condition studied**

induction of labor

**ICD-10 code**

O80

**ICD-10 code description**

Single spontaneous delivery

**Primary outcomes****1****Description**

preinduction cervical ripening

**Timepoint**

12 to 48 hours after intervention

**Method of measurement**

Clinical examinations

**Secondary outcomes****1****Description**

Use of induction

**Timepoint**

12 to 48 hours after entries

**Method of measurement**

Clinical examinations

**2****Description**

Type of delivery

**Timepoint**

12 to 48 hours after entries

**Method of measurement**

Clinical examinations

**3****Description**

Infant status

**Timepoint**

12 to 48 hours after entries

**Method of measurement**

Clinical examinations

**4****Description**

Possible complication

**Timepoint**

12 to 48 hours after entries

**Method of measurement**

Clinical examinations

**Intervention groups****1****Description**

Group 1: A suppository of Prostaglandin E2 (3mg.), Oxytocine (High Dose, with 6MIU starts and every 20 minutes if needed to be added to eight drops of up to 64 drops can be increased).

**Category**

Treatment - Drugs

## 2

### Description

Group 2: A Foley catheter of No. 16, Oxytocine (High Dose, with 6MIU starts and every 20 minutes if needed to be added to eight drops of up to 64 drops can be increased).

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yahyanejad Educational Center

##### Full name of responsible person

Dr. Shahla Yazdani

##### Street address

Yahyanejad Educational Center

##### 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

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

### Full name of responsible person

Nargess Gholizadeh Pasha

### Position

M.A/Responsible for Public Affairs Research Center

### Other areas of specialty/work

### Street address

Noshirvani street

### City

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### Postal code

4719173716

### Phone

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ngh\_pa@yahoo.com , zahra@mubabol.ac.ir

### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Department of Obstetrics and Gynecology, Ayatollah Rouhani Educational Center

#### Full name of responsible person

Dr. Shahla Yazdani

#### Position

Gynecologist

#### Other areas of specialty/work

#### Street address

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#### Name of organization / entity

Fatemehzahra Fertility & reproductive Health Research Center

#### Full name of responsible person

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#### Position

M.A/Responsible for Public Affairs Research Center

#### Other areas of specialty/work

#### Street address

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**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*