

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

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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

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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

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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

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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