Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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

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
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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
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Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Gangafroz Avenue
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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
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Person responsible for scientific inquiries

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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