

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Misoprostol versus foley catheter for cervical ripening in women with preeclampsia or gestational hypertension.

Protocol summary

Summary

The aim of this study is to compare the effect of misoprostol and foley catheter in cervical ripening among pregnant women with preeclampsia or gestational hypertension. The primary outcome was the interval between the commencement of induction and obtaining bishop score of 6 (induction to ripened cervix interval) and the secondary outcome included: maternal and neonatal complications, oxytocin requirement, delivery before 24 hours, duration of the second stage of delivery, cesarean delivery incidence in each of cervical ripening methods. Therefore, this interventional study was designed as a randomized control trial which was non-blinded and parallel. Inclusion criteria were pregnant women with preeclampsia or gestational hypertension and singleton pregnancies, gestational age of 26 weeks or more, absence of active labour, cephalic presentation, unfavorable cervix (bishop score of 6 or less), normal FHR and intact membrane. Exclusion criteria were hypersensitivity to Prostaglandins, previous Cesarean section or previous uterine scar, macrosomia, lethal congenital anomalies and placenta previa. According to this, a total number of 125 women were randomly divided into two groups. The misoprostol group (n=54) and the Foley catheter group (n=71). In group one, 25 µg of misoprostol tablet was administrated sublingually every 4 hours up to maximum dose of 6. In group two, a 16F Foley catheter was placed through the internal os of the cervix under aseptic condition and then inflated with 60 cc of sterile saline.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010731725N1**

Registration date: **2017-02-20, 1395/12/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

Elahe Hassanzadeh

Name of organization / entity

mashhad university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Misoprostol versus foley catheter for cervical ripening in women with preeclampsia or gestational hypertension.

Public title

Comparison between Misoprostol and foley catheter for cervical ripening.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- pregnant women with preeclampsia or gestational hypertension 2- Singleton pregnancy 3- Gestational age of 26 weeks or more 4- Absence of active labour 5- Cephalic presentation 6- Unfavorable cervix (bishop score of 6 or less) 7- Normal FHR 8- Intact membrane. Exclusion Criteria: 1- Hypersensitivity to Prostaglandins 2- Previous Cesarean section 3- Previous uterine scar 4- Macrosomia 6- lethal congenital anomalies 7- Placenta previa.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **125**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Mashhad University of Medical Sciences

Street address

Daneshgah Street, Ghoreishi building

City

Mashhad

Postal code

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

IR.MUMS.REC.1394.498

Health conditions studied

1

Description of health condition studied

preeclampsia

ICD-10 code

O14.9

ICD-10 code description

Pre-eclampsia, unspecified

2

Description of health condition studied

gestational hypertension

ICD-10 code

O13

ICD-10 code description

Gestational [pregnancy-induced] hypertension without significant proteinuria

Primary outcomes

1

Description

Interval between induction commencement and obtaining bishop score of 6

Timepoint

During intervention

Method of measurement

In hour unit obtained by manual vaginal exam

Secondary outcomes

1

Description

delivery before 24 hours

Timepoint

up to 24 hours after intervention

Method of measurement

in hour unit obtained by questionnaire

2

Description

neonatal complications

Timepoint

up to 24 hours after birth

Method of measurement

questionnaire and apgar score

3

Description

oxytocin requirement

Timepoint

during intervention

Method of measurement

questionnaire

4

Description

maternal complications

Timepoint

24 hours after delivery

Method of measurement

questionnaire

5

Description

duration of the second stage of delivery

Timepoint

maximum 3 hours after complete dilatation and effacement

Method of measurement

in minute unit obtained by questionnaire

6

Description

cesarean delivery incidence

Timepoint

up to 48 hours after intervention

Method of measurement

percentage unit obtained by questionnaire

Intervention groups

1

Description

In misoprostol group: 25 micro grams of misoprostol tablet was administered sublingually every 4 hours up to maximum dose of 6 during cervical ripening.

Category

Treatment - Drugs

2

Description

In foley catheter group: A 16 F foley catheter was inserted through internal os of cervix under aseptic condition and it was inflated with 60 cc of sterile saline. This intervention was performed during cervical ripening and was ejected spontaneously or according to physician order or after 24 hours.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem Hospital

Full name of responsible person

Street address

City

Mashhad

2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research assistance of Mashhad University of Medical Sciences

Full name of responsible person

Hadi Mousavi

Street address

Azadi Square, Medical College

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research assistance of Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Elahe Hassanzadeh

Position

Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Mashhad university of medical Sciences

Full name of responsible person

Leila Pourali

Position

Assistant Professor

Other areas of specialty/work**Street address**

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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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Elahe Hassanzadeh