Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Elahe Hassanzadeh
Name of organization / entity
mashhad university of medical sciences
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Iran (Islamic Republic of)
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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 hypertention
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 salin. 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
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Medical Student
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad university of medical Sciences

Full name of responsible person
Leila Pourali

Position
Assistant Professor

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Person responsible for updating data

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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