Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the effects of the isosorbide mononitrate with misoprostol and misoprostol with placebo for cervical ripening in induction of labour in 41 week pregnancies.

Protocol summary

Summary

In this study, we will compare the threptic effect and complications of isosorbide mononitrate. First pregnancies aged more than 41 weeks will enrolled the study based on the first trimester sonography (before 20 weeks of gestation) or last menstrual period (LMP). Patients will be divided into two groups regard to random block method. And patients and physician will not be aware of administered package. Firstly, 25 mg vaginal misoprostol will be administered and will be followed by 40 mg vaginal isosorbide mononitrate or placebo. Fetal heart rate and uterine contractions will be monitored permanently. Maternal heart rate and blood pressure will be also measured each 30 minutes. Patients will be reevaluated every 6 hours for other misoprostol administration, and this will be continued for at least 6 dose or until more than 3 uterine contraction longer than 40 seconds each 10 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022426745N1**
Registration date: **2017-05-16, 1396/02/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-16, 1396/02/26

Registrant information

Name

Maryam Ghaffarian Omid

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad university of medical sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2017-04-27, 1396/02/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of the isosorbide mononitrate with misoprostol and misoprostol with placebo for cervical ripening in induction of labour in 41 week pregnancies.

Public title

Comparison the effects of the isosorbide mononitrate with misoprostol and misoprostol with placebo for cervical ripening in induction of labour in 41 week pregnancies.

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria are first pregnancies aged more than 41 weeks based on the sonography; with single;

normal fetus; and cephalic presentation with no complication and before induction bishop score less than 6. Exclusion criteria include known allergy for prostaglandins or mifepristone; any contraindication for induction (such as uterine scar); contraindications for mifepristone administration (like adrenal, renal or liver disease); major cephalopelvic disproportion; abnormal stress test; vaginal bleeding and sever oligohydramnios.

Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **186**
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
Mashhad University of Medical Sciences, Mashhad, Iran
Street address
Iran, Mashhad, Daneshgah St,Qoreishi Building
City
Mashhad
Postal code
1234567
Approval date
2016-08-20, 1395/05/30
Ethics committee reference number
IR.MUMS.fm.REC.1394.359

Health conditions studied

1

Description of health condition studied
prolonged pregnancy
ICD-10 code
O48
ICD-10 code description
Prolonged pregnancy

Primary outcomes

1

Description
fetal heart rate
Timepoint
each 30 minutes
Method of measurement
quantitative with sonography

Secondary outcomes

1

Description
maternal blood pressure
Timepoint
each 30 minutes
Method of measurement
quantitative with pressure indicator

Intervention groups

1

Description
25 mg vaginal misoprostol will be administered and will be followed by 40 mg vaginal isosorbide mononitrate
Category
Treatment - Drugs

2

Description
25 mg vaginal misoprostol will be administered and will be followed by vaginal placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ommolbanin hospital
Full name of responsible person
Dr. Masoumeh Mirteymori
Street address
Iran, Mashhad, Zarine cross road, Ayatollah Behjat St, Ayatollah Behjat 16.
City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Mashhad university of medical sciences

Full name of responsible person
Dr. Masoumeh Mirteymori

Street address
Iran, Mashhad, Zarine cross road, Ayatollah Behjat St, Ayatollah Behjat 16.

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Mashhad

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, 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
Ommolbanin hospital

Full name of responsible person
Dr. Masoumeh Mirteymori

Position
Gynecologist/ Assistant professor

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