

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

Country

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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

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

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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, 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**Street address**

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Position

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Person responsible for updating data

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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