

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Compare the effects of isosorbide mono nitrate and misoprostol for cervical ripening for labor in term pregnancy

Protocol summary

Summary

The aim of the study was to compare the effect of Nitric Oxide (Isosorbide Mononitrate) versus Misoprostol in cervix ripening and labor progression. This study is a randomized clinical . Women with term pregnancies will refer for induction of labor with bishop score of 6 or less are randomly allocated to receive either 40 - mg isosorbide mononitrate (IMN) tablet vaginalley or 25- microgram misoprostol vaginally every 6 hours for maximum of three doses. The Inclusion criteria is contain term pregnancy having indication for termination; Bishop score less than 6; not using another method for cervical ripening. Exclusion criteria: preterm pregnancies; Bishop-score of 6; coagulation disorder; Cesarean section; severe preeclampsia; primary hypo tension; any type of heart disease; using any medication for heart disease, anticoagulants, contortionists and history for adrenal disease. Variables including: 1. Bishop score 2. Age 3. parity 4. Type drug 5. Need to augment 6. the time of effect 7. contractions hypertension 8. Apgar.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031233025N1**

Registration date: **2017-04-12, 1396/01/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

Name

Marzieh Lotfalizade

Name of organization / entity

Mashhad university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

lotfalizadem@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effects of isosorbide mono nitrate and misoprostol for cervical ripening for labor in term pregnancy

Public title

Compare the effects of isosorbide mono nitrate and misoprostol for cervical ripening for labor in term pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: term pregnancy having indication for termination; Bishop score less than 6; not using another method for cervical ripening. Exclusion criteria: preterm pregnancies; Bishop-score of 6; coagulation disorder; Cesarean section; severe preeclampsia; primary hypo tension; any type of heart disease; using any medication

for heart disease, anticoagulants, contortionists and history for adrenal disease.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Daneshgah Street.

City

Mashhad

Postal code

Approval date

2010-10-28, 1389/08/06

Ethics committee reference number

89886

Health conditions studied

1

Description of health condition studied

Term pergnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Apgar score

Timepoint

after intervention

Method of measurement

According to expert examination

Secondary outcomes

1

Description

Bishop Scale

Timepoint

After intervention

Method of measurement

According to expert examination

2

Description

Effective time

Timepoint

After intervention

Method of measurement

Hours

3

Description

Hypertension et contractions

Timepoint

After intervention

Method of measurement

According to expert examination

Intervention groups

1

Description

40 mg Isosorbide Mononitrate will be given ever 6 hours in 3 dose At intervals of 0, 6 and 12 hours.

Category

Treatment - Drugs

2

Description

25 µg misoprostol will be given ever 6 hours in 3 dose At intervals of 0, 6 and 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology and Obstetrics department , Imam Reza Hospital

Full name of responsible person

Secretary

Street address

Imam Reza Hospital, Taghi Abad Square,
Mashhad,Iran

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Marjan Ardakanian

Street address

Mashhad University of Medical Sciences, Daneshgah
Street.

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

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

Marzieh Lotfalizade

Position

Faculty member

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

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Mashhad University of Medical Sciences

Full name of responsible person

Dr. Marzieh Lotfalizade

Position

Gynecologist

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Mashhad University of Medical Sciences

Full name of responsible person

Farideh Golhasani

Position

MSc

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

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Fax**Email****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