Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Department of Obstetrics and Gynecology, Imam Reza Hospital, Mashhad, Iran
City
Mashhad
Postal code
Phone
+98 51 3802 2608
Fax
Email
lotfalizadem@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Marzieh Lotfalizade
Position
Gynecologist
Other areas of specialty/work
Street address
Department of Obstetrics and Gynecology, Imam Reza Hospital
City
Mashhad
Postal code
Phone
+98 51 3802 2608
Fax
Email
lotfalizadem@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farideh Golhasani
Position
MSc
Other areas of specialty/work
Street address
Woman Health Resaerch Center, Imam Reza Hospital, Mashhad, Iran
City
Mashhad
Postal code
00989137913316
Phone
+98 51 3802 2631
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