

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of isosorbide mononitrate on cervical ripening in outpatient pregnant women with unfavorable cervix.

Protocol summary

Study aim

Evaluating the effects of outpatient administration of isosorbide mononitrate on cervical ripening.

Design

Double blind, randomized controlled clinical trial with a parallel group on 145 pregnant women with a gestational age of 39-41 weeks

Settings and conduct

The study was performed in Akbarabadi teaching hospital. Eligible women were randomly divided into two groups of intervention (isosorbide receiving) and control (placebo administration). Researcher, patients and outcome assessors, were not aware of the groups to which participants were allocated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pregnant women with a gestational age of 39 - 40 weeks, intact membranes, Bishop Score < 6, singleton and cephalic presentation. Exclusion criteria: age of less than 18 years, urgent indication for pregnancy termination, antihypertensive therapy, fetal death and contraindications for treatment with Isosorbide mononitrate.

Intervention groups

Isosorbide-5-mononitrate capsules or placebo were inserted in the posterior vaginal fornix for two consecutive days (50 mg per day).

Main outcome variables

Main outcome variables: Bishop score 48 hours after intervention; Frequency of vaginal delivery; gestational age at the onset of spontaneous labor and interval between intervention to delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091023002624N27**

Registration date: **2018-08-24, 1397/06/02**

Registration timing: **retrospective**

Last update: **2018-08-24, 1397/06/02**

Update count: **0**

Registration date

2018-08-24, 1397/06/02

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2018-02-09, 1396/11/20

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2018-02-09, 1396/11/20

Trial completion date

empty

Scientific title

Evaluation of the efficacy of isosorbide mononitrate on cervical ripening in outpatient pregnant women with unfavorable cervix.

Public title

Effects of isosorbide mononitrate on cervical ripening

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant Gestational age of 39 - 41 weeks Intact membrane Bishop Score < 6 Singleton Cephalic presentation Maternal age between 18- 40 years old

Exclusion criteria:

Anti-hypertensive therapy Fetal death Known hypersensitivity to isosorbide mononitrate Aortic stenosis Obstructive myocardial hypertrophy Systolic blood pressure < 95 mm Hg Cardiovascular collapse

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **142**

Actual sample size reached: **145**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible women were randomly assigned into two groups of drug and placebo. Randomization was performed using sealed envelopes and participants were divided in four blocks; A, B, C, D. Groups A and C received drug and groups B and D received placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

Researcher, patients and outcome assessors, were not aware of the groups to which participants were allocated. The placebo was completely similar to isosorbide mononitrate in shape, taste and smell, and was made by the same manufacturer.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway, Chamran Highway Cross.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.IUMS.REC 1395.9211290004

Health conditions studied

1

Description of health condition studied

Cervical ripening in pregnancy.

ICD-10 code

O34.4

ICD-10 code description

Maternal care for other abnormalities of cervix

2

Description of health condition studied

Prolonged pregnancy

ICD-10 code

O48.1

ICD-10 code description

Prolonged pregnancy

3

Description of health condition studied

Failed medical induction of labour

ICD-10 code

O61.0

ICD-10 code description

Failed medical induction of labor

Primary outcomes

1

Description

Bishop scores 48 hours after intervention

Timepoint

48 hours after intervention

Method of measurement

Vaginal examination

Secondary outcomes

1

Description

Frequency of vaginal delivery

Timepoint

At birth

Method of measurement

Data sheets

2

Description

Gestational age at the onset of spontaneous labor

Timepoint

Onset of spontaneous labor

Method of measurement

Data sheets

3

Description

Interval between intervention to delivery

Timepoint

At delivery

Method of measurement

Data sheets

Intervention groups

1

Description

Intervention group: Two capsules of 50 mg isosorbide-5-mononitrate were inserted in the posterior vaginal fornix in two consecutive days (50 mg per day).

Category

Treatment - Drugs

2

Description

Control group: Two capsules of placebo, were inserted in the posterior vaginal fornix by the researcher in two consecutive days (50 mg per day).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Hospital

Full name of responsible person

Maryam Kashanian

Street address

Molavi street, Molavi cross.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

SeyyedKazem Malakouti

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Illam University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Maryam Kashanian

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available