

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparative study of the effect of vaginal isosorbide dinitrate in pre-induction cervical ripening in term pregnancy

Protocol summary

Study aim

Comparative study of the effect of vaginal isosorbide dinitrate in pre-induction cervical ripening in term pregnancy

Design

This is single blind clinical trial. The study population included all patients referring to Imam Reza hospital in Kermanshah city. A total of 148 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study, which will be conducted at Imam Reza Hospital in Kermanshah city. The participants do not know what medicine they will receive, and at the beginning of the study, the vital signs of the participants in both groups are recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: no history of previous cesarean section or any uterine scar; single pregnancy. Exclusion criteria: estimate fetal weight more than 4 kg; labor pain.

Intervention groups

The first intervention group will receive 40 mg of vaginal isosorbide dinitrate within 24 hours. The second intervention group will receive 20 mg of vaginal isosorbide dinitrate within 24 hours. The third intervention group will receive 10 mg of vaginal isosorbide dinitrate within 24 hours. The control group will not receive any intervention.

Main outcome variables

Headache, nausea, blood pressure drop

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N90**

Registration date: **2018-05-02, 1397/02/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-02, 1397/02/12**

Update count: **0**

Registration date

2018-05-02, 1397/02/12

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-28, 1397/02/08

Expected recruitment end date

2018-10-30, 1397/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of vaginal isosorbide dinitrate in pre-induction cervical ripening in term pregnancy

Public title

Comparison the effect of vaginal isosorbide dinitrate in pre-induction cervical ripening in term pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age 37 weeks up to the end of the week
Cephalic presentation No contraindications for isosorbide dinitrate Normal body volume index (BMI = 19.8-26), No history of previous cesarean section or any uterine scar

Exclusion criteria:

The presence of systemic diseases Estimate fetal weight more than 4 kg Vaginal bleeding Intolerance to ISDN, labor pain and oligohydramnios

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients will be blinded to the study groups, dosage of the drug and the manufacturer of the drug

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-01-31, 1396/11/11

Ethics committee reference number

IR.KUMS.REC.1396.594

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

Z34

ICD-10 code description

Normal pregnancy

Primary outcomes

1

Description

Headache

Timepoint

At the beginning of the study, every 15 minutes to 1 hour, then every 30 minutes to 2 hours, and every 1 hour until delivery

Method of measurement

Ask the patient

2

Description

Nausea

Timepoint

At the beginning of the study, every 15 minutes to 1 hour, then every 30 minutes to 2 hours, and every 1 hour until delivery

Method of measurement

Ask the patient

3

Description

Blood pressure drop

Timepoint

At the beginning of the study, every 15 minutes to 1 hour, then every 30 minutes to 2 hours, and every 1 hour until delivery

Method of measurement

Sphygmomanometer.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 40 mg of vaginal isosorbide dinitrate within 24 hours

Category

Treatment - Drugs

2

Description

The second intervention group will receive 20 mg of vaginal isosorbide dinitrate within 24 hours

Category

Treatment - Drugs

3

Description

The third intervention group will receive 10 mg of vaginal isosorbide dinitrate within 24 hours

Category

Treatment - Drugs

4

Description

The control group will not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Fatemeh Poyan

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 4601

Email

fatemehpoyan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

fatemeh poyan

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 4601

Email

fatemehpoyan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Negin Rezavand

Position

Gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6309

Email

NRezavand@kums.ac.ir

Email

fatemehpoyan@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

fatemeh poyan

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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City

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