

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The Effect of Vaginal Isosorbide Mononitrate Administration on Cervical Ripening before Induction of Labor in primigravida

#### Protocol summary

##### Study aim

to determine the effect of vaginal Isosorbide Mononitrate administration on cervical ripening before induction of labor

##### Design

This study is a single-blind clinical trial with two parallel group. Samples are randomly divided into control and intervention groups using random number table. The sample size for each group was calculated to be 32 persons. The phase of this clinical trial is 3.

##### Settings and conduct

This study is performed on primigravida women who referred to the 22 Bahman and Aria hospitals. In the intervention group, 40 mg Isosorbide Mononitrate tablet and in control group one vitamin C tablet as placebo was placed in the posterior vaginal fornix. After 12 hours, If Bishop score is <6, the isosorbide mononitrate vaginal tablets will be used again and Bishop score is re-measured 12 hours later. After the second visit, patients are induced with oxytocin.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: primigravida mothers with gestational age over 40 weeks; singleton pregnancy; fetus in a Cephalic presentation presentation with a Bishop score < 4 Exclusion criteria: Previous scar on the uterus; polyhydramnios, blood pressure > 160/ 110; proteinuria ≥1; history of intolerance to isosorbide mononitrate; candidates for cesarean section

##### Intervention groups

The intervention group will be prescribed , 40 mg Isosorbide Mononitrate tablet (manufactured by Arya pharmaceutical company) and control group received one vitamin C tablet (manufactured by dr.abidi pharmaceutical company).

##### Main outcome variables

changes in Bishop score; duration of hospitalization to active phase (3-4 cm dilatation); side effects of drug (palpitations and headache in mother); delivery method (natural or cesarean section)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191018045150N1**

Registration date: **2020-04-27, 1399/02/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-27, 1399/02/08**

Update count: **0**

##### Registration date

2020-04-27, 1399/02/08

##### Registrant information

##### Name

samane raffe

##### Name of organization / entity

Islamic azad university of mashhad

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3890 9438

##### Email address

akbari-mo@mashhad.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-04, 1398/11/15

##### Expected recruitment end date

2020-08-05, 1399/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The Effect of Vaginal Isosorbide Mononitrate Administration on Cervical Ripening before Induction of Labor in primigravida

## Public title

The Effect of Vaginal Isosorbide Mononitrate Administration on Cervical Ripening before Induction of Labor

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

primigravida mother who have gestational age over 40 weeks. primigravida mother who have singleton pregnancy. primigravida mother who have fetus in a Cephalic presentation with a Bishop score < 4.

### Exclusion criteria:

Full term Primigravida who have Previous scar on the uterus. Full term Primigravida who have polyhydramnios Full term Primigravida who have blood pressure > 160/110 Full term Primigravida who have proteinuria  $\geq$  1 Primigravida who have a history of intolerance to isosorbide mononitrate Primigravida who are candidates for cesarean section

## Age

No age limit

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization method and random number table have been used to assign individuals to groups. In this method, a random point(a number) is first selected and then the numbers in the right-to-left and top-down are read as a single digit. Intervention group with isosorbide was assigned with 0, 1, 2, 3 and 4 numbers, and 5, 6, 7, 8 and 9 numbers were assigned to control group with placebo.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this way, since both the drug and the placebo are used, the participant does not know which of the two control or intervention groups belong to.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Islamic Azad University of Mashhad

##### Street address

Shahinfar Medical School, Shahinfar street, Imam Khomeini street

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9146978831

#### Approval date

2018-03-14, 1396/12/23

#### Ethics committee reference number

IR.IAU.MSHD.REC.1396.142

## Health conditions studied

### 1

#### Description of health condition studied

cervical ripening

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

bishop score

#### Timepoint

Bishop's score is measured before the intervention, 12 hours after the first visit, and every 4 hours after the second visit.

#### Method of measurement

bishop score scale

## Secondary outcomes

### 1

#### Description

Mother's blood pressure

#### Timepoint

Mother's blood pressure is measured before the intervention, 12 hours after the first visit, and every 4 hours after the second visit.

#### Method of measurement

Mercury Barometer

## Intervention groups

## 1

### Description

Intervention group: . In the intervention group, 40 mg Isosorbide Mononitrate tablet(manufactured by Arya pharmaceutical company) was placed in the posterior vaginal fornix. After 12 hours, If bishop score is <6, the isosorbide mononitrate vaginal tablets will be used again and bishop score is re-measured 12 hours later. After the second visit, patients are induced with oxytocin.

### Category

Treatment - Drugs

## 2

### Description

Control group: In the control group, a vitamin c tablet(manufactured by dr.abidi pharmaceutical company) was placed in the posterior vaginal fornix. After 12 hours, If bishop score is <6, the vitamin c vaginal tablets will be used again and bishop score is re-measured 12 hours later. After the second visit, patients are induced with oxytocin.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Aria hospital, 22 Bahman hospital

#### Full name of responsible person

samane raffa

#### Street address

No. 18, Ladan 7, Ladan Boulevard,

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9146978831

#### Phone

+98 51 3890 9438

#### Email

akbari-mo@mashhad.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Islamic Azad University of Mashhad

#### Full name of responsible person

abtahi saeed

#### Street address

Shahinfar Medical School, Shahinfar street, Imam Khomeini street

#### City

mashhad

### Province

Razavi Khorasan

### Postal code

9187147578

### Phone

+98 51 3225 0041

### Email

akbari-mo@mashhad.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Islamic Azad University of Mashhad

### Proportion provided by this source

30

### Public or private sector

Private

### 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

Islamic azad university of mashhad

#### Full name of responsible person

Samane Raffa

#### Position

Faculty member

#### Latest degree

Master

#### Other areas of specialty/work

Nursery

#### Street address

No.18, 7 Ladan , Ladan blvd, mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9146978831

#### Phone

+98 51 3890 9438

#### Fax

#### Email

akbari-mo@mashhad.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Islamic Azad University of Mashhad

#### Full name of responsible person

zarif najafi

akbari-mo@mashhad.ir

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Shahinfar Medical School, Shahinfar street, Imam  
Khomeini street

**City**

mashhad

**Province**

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**Postal code**

9187147578

**Phone**

00095132250041

**Email**

akbari-mo@mashhad.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University of Mashhad

**Full name of responsible person**

samane

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

No. 18, Ladan 7, Ladan Boulevard

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9146978831

**Phone**

+98 51 3890 9438

**Email**

**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**

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

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All individual data and study protocols can be shared after unidentifiable individuals.

**When the data will become available and for how long**

Start access period 4 months after printing results

**To whom data/document is available**

Our data will only be available to researchers working in Academic and scientific institutions

**Under which criteria data/document could be used**

The use of data should be done with the permission of Mashhad Azad University Research Assistant

**From where data/document is obtainable**

Vice chancellor for research, Mashhad Azad University, address:

<http://mshdiau.ac.ir/moavenathaa/vice-chancellor-of-research>

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

Firstly, the request should be sent to the Vice Chancellor for Research of Mashhad Azad University. After obtaining a license, a transcript of the request will be sent to the person responsible for the study and data will be sent via email

**Comments**