Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 scoreis 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 pressre> 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 pressre> 160/110 Full term Primigravida who have proteinuria ≥ 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 raffe

Street address
No. 18, Ladan 7, Laden Boulevard,

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Phone
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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

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9187147578

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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
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 Raffe

Position
Faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

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No.18, 7 Ladan , Ladan blvd, mashhad

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University of Mashhad

Full name of responsible person
zarif najafi

Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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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
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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