Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of magnesium sulfate vaginal gel on cervical ripening and induction of labor in nulliparous women: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of magnesium sulfate vaginal gel on cervical ripening and induction of labor

Design

The double-blind randomized controlled clinical trial with a total of 174 samples. Samples were randomly selected using computer software (http://www.random.org) through random block sizes of three and six blocks in three groups of 58 people.

Settings and conduct

This study will be performed in Shahid Taleghani Hospital in Ilam. The study is double-blind and the pregnant woman and the medical staff are kept unaware of the type of treatment. In the first group, magnesium sulfate vaginal gel contains 6 grams of magnesium sulfate, in the second group, magnesium sulfate vaginal gel contains 4 grams of magnesium sulfate, and in the control group, placebo is placed on the cervix through vaginal examination. 4 hours later, all participants are examined. If no change is observed, another dose of the same intervention is performed and re-examined 4 hours later.

Participants/Inclusion and exclusion criteria

Nuliparous, body mass index 18.5-25, post date gestational age, bishop score on arrival less than 4, single fetus with cephalopelvic presentation and intact membranes, low-risk pregnancy and indication for labor induction.

Intervention groups

The first group, magnesium sulfate vaginal gel contains 6 grams of magnesium sulfate, in the second group, magnesium sulfate vaginal gel contains 4 grams of magnesium sulfate, and in the control group, placebo contains the same materials used in the gel except magnesium sulfate.

Main outcome variables

Average bishop score; The amount of misoprostol used; Length of labor; Type of delivery; Frequency of complications; Oxytocin level used, Duration of maternal hospitalization; Apgar score of the first and fifth minutes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210105049944N1**
Registration date: **2021-03-06, 1399/12/16**
Registration timing: **prospective**

Last update: **2021-03-06, 1399/12/16**
Update count: **0**

Registration date

2021-03-06, 1399/12/16

Registrant information

Name

Zahra Chenari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8331

Email address

chenari.z@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of magnesium sulfate vaginal gel on cervical ripening and induction of labor in nulliparous women: a randomized controlled clinical trial

Public title
The effectiveness of magnesium sulfate vaginal gel on cervical ripening and induction of labor in nulliparous women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Desire to participate in the study Being nulliparous Mother age 18-40 years Body mass index 18.5-25 Post date gestational age Bishop score less than 4 Single fetus with cephalic presentation and intact membranes Estimated weight of the fetus 2500-4000 grams Low risk pregnancy Indication of labor induction
Exclusion criteria:
Risky underlying disease (anemia, blood disorders, heart or lung disease, connective tissue and smooth muscle problems) History of any uterine scar Refer with bleeding or rupture of membranes Multiple pregnancy Diagnosis of cephalopelvic disproportion by a physician Contraindications to use of magnesium sulfate Patient non-cooperation
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **174**
Randomization (investigator's opinion)
Randomized
Randomization description
To determine the allocation sequence, 3 and 6 blocking methods with 1: 1 allocation ratio are used. After listing almost all possible states of the blocks and assigning a number to each of them, the assignment sequence will be determined using a computer random number table (using WWW.Randomizer.org). The randomization list is prepared by a statistician. To conceal the type of intervention, it is written on paper and numbered in a series of sealed opaque matte envelopes. By attending the study hospital, the researcher will open an envelope for each research sample in the order of their numbers and the type of intervention will be determined.
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo is used in the same shape and packaging as magnesium sulfate gel. Pregnant women and medical staff are kept unaware of the type of treatment provided.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Esfand Ave, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2021-02-13, 1399/11/25
Ethics committee reference number
IR.AJUMS.REC.1399.890

Health conditions studied

1

Description of health condition studied
Cervical ripening and induction of labor
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Average of Bishop score
Timepoint
Before the intervention, 4 hours after the intervention, 8 hours after the intervention
Method of measurement
Vaginal examination, Bishop score table

Secondary outcomes

1

Description
The length of labor

Timepoint
End of the study
Method of measurement
Partograph form

2

Description
Probable complications of magnesium sulfate
Timepoint
4 hours after the start of the intervention, 8 hours after the start of the intervention
Method of measurement
Questionnaire

3

Description
Number of doses of misoprostol used
Timepoint
End of the study
Method of measurement
Hospital file

4

Description
Type of delivery
Timepoint
End of the study
Method of measurement
Hospital file

5

Description
Number of doses of oxytocin used
Timepoint
End of the study
Method of measurement
Hospital file

6

Description
Duration of hospitalization of mother
Timepoint
End of the study
Method of measurement
Hospital file

7

Description
APGAR score of the first and fifth minutes
Timepoint
End of the study
Method of measurement
Hospital file

Intervention groups

1

Description
Intervention group: The first group receives magnesium sulfate vaginal gel containing 6 grams of magnesium sulfate prepared by the Industrial Laboratory of the Faculty of Pharmacy, Ahvaz Jundishapur University of Medical Sciences. Participants receive the gel as soon as they are admitted and all participants are examined 4 hours later. If there is no change, another dose of the same intervention is performed and re-examined 4 hours later.
Category
Treatment - Drugs

2

Description
Intervention group: The second group receives magnesium sulfate vaginal gel containing 4 grams of magnesium sulfate prepared by the Industrial Laboratory of the Faculty of Pharmacy, Ahvaz Jundishapur University of Medical Sciences. Participants receive the gel as soon as they are admitted and all participants are examined 4 hours later. If there is no change, another dose of the same intervention is performed and re-examined 4 hours later.
Category
Treatment - Drugs

3

Description
Control group: The third group received a placebo containing the same materials used in magnesium sulfate vaginal gel except magnesium sulfate in a similar shape and package prepared by the Industrial Laboratory of the Faculty of Pharmacy, Ahvaz Jundishapur University of Medical Sciences. Participants receive the gel as soon as they are admitted and all participants are examined 4 hours later. If there is no change, another dose of the same intervention is performed and re-examined 4 hours later.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Taleghani hospital
Full name of responsible person
Zahra Chenari
Street address
Shahid Taleghani hospital, Khabarnegar Blvd, Shahid Behshti Blvd
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Kurosh zarea
Street address
Esfand Ave, Golestan Blvd
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+98 61 3373 8333
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zarea-k@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Zahra Chenari
Position
MS.c Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Ahvaz University of Medical Sciences
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Position
Associate Professor
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Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zahra Chenari
Position
MS.c student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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chenari.z@ajums.ac.ir

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