

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

Nulliparous, 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

City

Ilam

Province

Ilam

Postal code

6931975397

Phone

+98 84 3337 2621

Email

chenari.z@ajums.ac.ir

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

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8333

Email

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

Street address

Esfand Ave, Golestan Blvd

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8331

Email

chenari.z@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Mina Iravani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Esfand Ave, Golestan Blvd

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8331

Email

iravani-m@ajums.ac.ir

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

Street address

Esfand Ave, Golestan Blvd

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8331

Email

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