

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of local administration of magnesium sulfate in the latent phase of labor on the improvement of effacement, dilatation, and duration of labor in primiparous and multiparous women

Protocol summary

Study aim

Comparison of the effectiveness of local administration of magnesium sulfate in the latent phase of labor on the improvement of effacement, dilatation, and duration of labor in primiparous and multiparous women

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, phase 3, which will be conducted on 75 women admitted in the delivery room of Ayatollah Mousavi Hospital in Zanjan. People will be assigned to two intervention groups and one control group using a random sampling method of 6 blocks.

Settings and conduct

The setting is the delivery room of Ayatollah Mousavi Hospital in Zanjan. The samples will be allocated to two intervention groups and one control group by a random block method of 6. The intervention group will receive ten cc of 50% magnesium sulfate in the latent phase of labor. Distilled water will be used for the placebo group with the same prescription. The study will be double-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria Pregnant women with a singleton pregnancy, The cephalic presentation, Gestational age 42 - 37 weeks, Age of women between 18-35 years, Spontaneous start of labor, Dilatation less than 3 cm, Body mass index between 19.8 and 30 kg/m², Low-risk pregnancy Exclusion criteria Receiving infertility treatments, multiple pregnancies, History of heart disease, Having a history of a severe allergy to magnesium sulfate, The existence of contraindications for natural childbirth

Intervention groups

Ten cc of 50% magnesium sulfate (up to two doses) will be poured between the fingers on the cervix during the vaginal examination during the latent phase of labor to cover the entire cervix. Distilled water will be used for

the placebo group with the same prescription.

Main outcome variables

Effacement, Dilatation, and Duration of Labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231121060128N1**

Registration date: **2024-01-01, 1402/10/11**

Registration timing: **prospective**

Last update: **2024-01-01, 1402/10/11**

Update count: **0**

Registration date

2024-01-01, 1402/10/11

Registrant information

Name

Zahra Rahemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-07-10, 1403/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of local administration of magnesium sulfate in the latent phase of labor on the improvement of effacement, dilatation, and duration of labor in primiparous and multiparous women

Public title

Comparison of the effectiveness of local administration of magnesium sulfate in the latent phase of labor on the improvement of effacement, dilatation, and duration of labor in primiparous and multiparous women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Singleton pregnancy Cephalic presentation Gestational age, 37-42 weeks Dilatation less than 3 cm Body mass index between 19.8 and 30 kg/m² Low risk pregnancy

Exclusion criteria:

The infertility treatments in a recent pregnancy Multiple pregnancy History or heart disease in recent pregnancy Having a history of severe allergy to magnesium sulfate The existence of contraindications for natural childbirth, including fetal heart rate disorders, placental abruption, umbilical cord prolapse known pelvic stenosis disorder before the start of labor

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible people will be selected during regular visits and then will be assigned to two intervention groups and one control group using a random sampling method of 6 blocks. For this purpose, blocks of 6 will be selected using a table of random numbers so that the sample size reaches 75 people. Blocking will be done by a person not involved in sampling. Each of the generated random sequences will be recorded on a card and the cards will be placed in the envelopes. Finally, the lids of the envelopes will be glued and placed inside a box. At the start of the intervention to identify the order of the participants, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double-blind. Pregnant women and the person controlling the progress of labor and delivery will not know about the grouping and type of intervention. Examinations and registration of labor progress in the latent phase will be done and recorded every 4 hours by a research associate.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

Street address

Azadi Square, Central Building of Zanjan University of Medical Sciences, The first floor of the vice-chancellor for research and technology, Zanjan University of Medical Sciences, Zanjan

City

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Province

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Postal code

4515613191

Approval date

2023-11-14, 1402/08/23

Ethics committee reference number

IR.ZUMS.REC.1402.193

Health conditions studied**1****Description of health condition studied**

Improvement of dilation, effacement of cervix , and labor duration

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Cervical effacement, dilation, and duration of labor

Timepoint

Before the intervention, 4 hours and then 8 hours after the intervention

Method of measurement

Vaginal examination

2

Description

Hemoglobin and hematocrit

Timepoint

24 hours after delivery

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Ten cc of 50% magnesium sulfate (up to two doses) will be poured between the fingers on the cervix during the vaginal examination during the latent phase of labor to cover the entire cervix. During the first half hour after using the medicine, the mother will be asked to rest on the bed in order to better absorb the medicine. In case of rupture of the fetal membranes during or less than half an hour after the local use of the drug, 10 cc of magnesium sulfate will be used again after the end of active shedding.

Category

Treatment - Drugs

2

Description

During the latent phase of labor, ten cc of distilled water (up to two doses) will be poured between the fingers on the cervix during the vaginal examination to cover the entire cervix.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital of Zanjan

Full name of responsible person

Zahra Rahmi

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Gavazang Boulevard, Ayatollah Mousavi Zanjan Hospital, Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zanjan University of Medical Sciences

Proportion provided by this source

100

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

Zanjan University of Medical Sciences

Full name of responsible person

Zahra Rahmi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available