

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Investigating the effect of vaginal magnesium sulfate in preparing the cervix before labor induction

Protocol summary

Study aim

Investigating the effect of vaginal magnesium sulfate in preparing the cervix before labor induction

Design

A clinical trial with a control group, with parallel groups, three blinded, randomized, phase 3 on 104 patients. Computer random assignment software was used for randomization.

Settings and conduct

The study is a triple-blinded clinical trial in Imam Khomeini and Razi Hospitals in Ahvaz. Completely similar vials containing normal saline and magnesium sulfate will be used without drug labels. These vials will be labeled with an A or B code by a research colleague. They will be separated from each other and the patient and the examiner and the researcher and the analyst will be completely unaware of its nature. In the initial examination, Bishop's score will be determined for the patient, then cotton soaked with 5cc of vial A or B is placed in the patient's cervix, and 3 hours later, the patient will be examined again and the secondary Bishop's score will be determined. The duration of labor and the active phase of labor are measured in each patient

Participants/Inclusion and exclusion criteria

Pregnant women 18_35 years BMI:19.8_30 Gestational age 34_42 week by first trimester sonography A single alive fetus with cephalic presentation and 2500_4000 gr by sonography Bishop score below 5 Having Indication of labor induction The exclusion criteria :contraindications for induction of labor and lack of consent to participate in the study

Intervention groups

Control group:Cotton soaked in 5 cc of normal saline will be placed in the patient's vagina Intervention group:Cotton soaked in 5 cc of magnesium sulfate will be placed in the patient's vagina

Main outcome variables

Primary and secondary Bishop score, type of labor, total

length of labor, length of the active phase of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230612058462N1**

Registration date: **2023-10-09, 1402/07/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-09, 1402/07/17**

Update count: **0**

Registration date

2023-10-09, 1402/07/17

Registrant information

Name

Ayeh Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3337 4753

Email address

s.r.musavi88@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-20, 1402/05/29

Expected recruitment end date

2024-04-17, 1403/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vaginal magnesium sulfate in preparing the cervix before labor induction

Public title

The effect of vaginal magnesium sulfate in preparing the cervix before labor induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women 18_35 years BMI :19/8 _30 Gestational age 34_42 week by first trimester sonography A single alive fetus with cephalic presentation and 2500_4000 gr by sonography Having a Indication to labor induction

Exclusion criteria:

Having indications for cesarean section Lack of consent to participate in the study Having a history of cesarean section

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups of 52 people, A and B, using random assignment computer software, and the number of groups and samples are recorded in this software, and people are randomly assigned to two groups. The randomization list will be determined by the statistician.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study will be conducted in a triple-blind manner. Completely similar vials containing normal saline (placebo or placebo) and magnesium sulfate will be used without drug labels. These vials will be labeled with an A or B code by another research colleague. They will be separated from each other and the patient and the examiner and the researcher and the analyst will be completely unaware of its nature.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Ahvaz University of medical science

Street address

Ahvaz - Golestan - Koi Saadi - East Torbat Street - Plate 131

City

Ahvaz

Province

Khouzestan

Postal code

۶۱۳۶۸۵۴۷۷

Approval date

2023-08-25, 1402/06/03

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1402.029

Health conditions studied

1

Description of health condition studied

The effect of vaginal magnesium sulfate in preparing the cervix before induction of labor

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bishop score

Timepoint

Before intervention and after 3 hours

Method of measurement

According to Bishop score

2

Description

Total time of vaginal delivery

Timepoint

Since start labor induction till vaginal delivery

Method of measurement

Clock

3

Description

Time of active phase of labor

Timepoint

Since cervix dilatation 4cm till vaginal delivery

Method of measurement

Clock

4

Description

Type of delivery

Timepoint

After delivery

Method of measurement

View and Record file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Completely similar vials containing normal saline (placebo) and 50% magnesium sulfate from Shahid Ghazi Pharmaceutical Company of Tabriz, which are without drug labels, will be used. These vials will be labeled with an A or B code by another research colleague They will be separated, and the patient and the examiner, the researcher and the analyst will be completely unaware of its nature. In the initial examination, Bishop's score will be determined for the patient, then cotton soaked with 5 cc of vial A or B will be placed in the patient's cervix. 3 hours later, the patient will be examined again and the secondary Bishop score will be determined. Also, by entering the relevant code in the partograph form, the duration of labor and the active phase of labor were measured in each patient.

Category

Treatment - Drugs

2

Description

Control group: : Completely similar vials containing normal saline (placebo) and 50% magnesium sulfate from Shahid Ghazi Pharmaceutical Company of Tabriz, which are without drug labels, will be used. These vials will be labeled with an A or B code by another research colleague They will be separated, and the patient and the examiner, the researcher and the analyst will be completely unaware of its nature. In the initial examination, Bishop's score will be determined for the patient, then cotton soaked with 5 cc of vial A or B will be placed in the patient's cervix. 3 hours later, the patient will be examined again and the secondary Bishop score will be determined. Also, by entering the relevant code in the partograph form, the duration of labor and the active phase of labor were measured in each patient.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Seyede ayeh musavi

Street address

No.131.East torbat Ave.Quii saadi

City

Ahwaz

Province

Khouzestan

Postal code

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Phone

+98 61 3292 3985

Email

S.r.musavi88@gmail.com

Web page address

<https://www.ajums.ac.ir/>

2

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Seyede ayeh musavi

Street address

No.131.East torbat Ave.Quii saadi

City

Ahwaz

Province

Khouzestan

Postal code

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Web page address

<https://www.ajums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Doctor amir amani

Street address

No 131.East torbat.Quii saadi

City

Ahwaz

Province

Khouzestan

Postal code

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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

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

Seyede ayeh musavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

NO. 131 ,East Torbat Ave, saadi Qii

City

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Province

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Postal code

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Phone

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Fax**Email**

S.r.musavi88@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Seyede ayeh musavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Fax**Email**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Seyede ayeh musavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Phone

+98 61 3337 4753

Fax**Email**

S.r.musavi88@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

Data related to the main outcome of the study

When the data will become available and for how long

1 year after the publication of the article

To whom data/document is available

Medical students and gynecologists

Under which criteria data/document could be used

Request through personal email - use for academic research

From where data/document is obtainable

The applicant should send an email to the research unit of the university, after explaining the working method, the necessary information will be sent

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

Email your request to the research unit of the university and give a brief explanation about your work method or the details required from this study so that the details will be sent via email.

Comments