Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 trimesther sonograghy A single alive fetus with cephalic presentation and 2500 _4000 gr by sonograghy 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 sonograghy A single alive fetus with cephalic presentation and 2500_4000 gr by sonograghy 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
Ahwaz
Province
Khouzestan
Postal code
٦١٣٦٦٨٥٤٧٧
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
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Web page address
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2

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
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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
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Email
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Web page address
https://www.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
Seyede ayeh musavi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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NO. 131 ،East Torbat Ave، saadi Qii
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Person responsible for scientific inquiries

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Position
Resident
Latest degree
Medical doctor
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Person responsible for updating data

Contact
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Ahvaz University of Medical Sciences
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Seyede ayeh musavi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Fax
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S.r.musavi88@gmail.com
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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