Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the local effect of magnesium sulfate on cervical progression during labor in nulliparous women

Protocol summary

Study aim
Evaluation of the effect of topical magnesium sulfate on cervical progression

Design
A controlled clinical trial with randomized double-blind randomized parallel groups was performed on 88 patients.

Settings and conduct
492/5000 Location of Asalian Hospital, Lorestan University of Medical Sciences, 88 eligible patients will be included in the present study. In this way, a part of the table of random numbers is selected and AB code is used for 0 to 4 numbers and BA code is used for 5 to 9 numbers. In this study, code A represents the group receiving magnesium sulfate and code B represents the placebo group.

Participants/Inclusion and exclusion criteria
Inclusion criteria for women between 18-35 years of age are primiparous, gestational age 37-42 full weeks live live single fetus with fetal head weight estimate between 2500-4000 g Spontaneous onset of labor process, low risk pregnancy and body mass index 8.19 -30 kg per square meter. Exclusion criteria: fetal heart rate abnormalities, placental abruption and umbilical cord prolapse.

Intervention groups
In the intervention group, after the onset of the active phase, which is dilated 3-5 cm with active uterine contractions and having a urine score of 5, the researcher pours 10 cc of 50% magnesium sulfate into the cervix from the fingertips with a 10 cc syringe by the examiner. . If a ruptured bladder is seen, 10 cc of magnesium sulfate is poured onto the cervix again. In the control group, distilled water is used instead of magnesium sulfate for blinding

Main outcome variables
Effect of magnesium sulfate on dilatation, effusion, cervical condition and cervical consistency

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090701002114N5**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **prospective**

Last update: **2020-09-07, 1399/06/17**
Update count: **0**

Registration date
2020-09-07, 1399/06/17

Registrant information

Name
Fatemeh Yari
Name of organization / entity
Lorestan university of medical sciences
Country
Iran (Islamic Republic of)
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+98 66 1222 6450
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-10, 1399/06/20

Expected recruitment end date
2020-11-10, 1399/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the local effect of magnesium sulfate on cervical progression during labor in nulliparous women

Public title
Effect of magnesium sulfate on cervical progression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women 18-35 years old Fetal age 37-42 full weeks live single fetus Estimated weight 2500-4000 gr Spontaneous onset of the labor process low risk pregnancy body mass index 19/8-30
Exclusion criteria:
Uncertain pattern of fetal heart rate Occurrence of placental abruption and umbilical cord prolapse's lack of patient cooperation and mismatch of fetal head with mother pelvis umbilical cord prolapse's lack of patient cooperation cephalopelvic disappropriation Based on the diagnosis of the treating physician
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
using the randomized block method, in the form of quadruple blocks in two double-blind intervention groups And control will be assigned. In this way, a part of the table of random numbers is selected and AB code is used for 0 to 4 numbers and BA code is used for 5 to 9 numbers. In this study, code A represents the group receiving magnesium sulfate and code B represents the placebo group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the fact that in the intervention group, 10 cc of magnesium sulfate 50% will be used topically through the vagina using a syringe, in the control group, under the same conditions, only distilled water instead of magnesium sulfate drug for blinding The researcher and the patient will be used. It should be noted that vials that are completely similar to distilled water and magnesium sulfate drug without a drug name label will be used. These vials will be separated by a label containing a code (by a specific pharmaceutical company) that the researcher is completely unaware of their nature.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Lorestan University of Medical Sciences
Street address
university campus complex, km 3 of Khorramabad-Borujerd road, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Approval date
2020-08-05, 1399/05/15
Ethics committee reference number
IR.LUMS.REC.1399.86

Health conditions studied

1

Description of health condition studied
Labor progress
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The effect of magnesium sulfate on cervical effacement
Timepoint
Every two hours until the cervix is fully open
Method of measurement
Through internal examination of the vagina, which is expressed as a percentage

2

Description
The effect of magnesium sulfate on cervical dilatation
Timepoint
Every two hours until the cervix is fully open
Method of measurement
Through an internal vaginal examination expressed in centimeters

3

Description

Effect of magnesium sulfate on cervical position
Timepoint
Every two hours until the cervix is fully
Method of measurement
Through an internal vaginal examination expressed in centimeters

4

Description
Effect of magnesium sulfate on cervical consistency
Timepoint
Every two hours until the cervix is fully
Method of measurement
Soft to medium hard

5

Description
Effect of magnesium sulfate on cervical position
Timepoint
Every two hours until the cervix is fully
Method of measurement
Anterior posterior medial

Secondary outcomes

1

Description
Effect of magnesium sulfate on Bishab score
Timepoint
Every two hours
Method of measurement
In terms of score

2

Description
Effect of magnesium sulfate on the duration of labor
Timepoint
Every two hours
Method of measurement
per second

Intervention groups

1

Description
Intervention group:. In the intervention group, after the onset of the active phase, which is dilated 3-5 cm with active uterine contractions and having a urine score of 5, the researcher pours 10 cc of 50% magnesium sulfate into the cervix from the fingertips with a 10 cc syringe by the examiner. Be. If a ruptured bladder is seen, 10 cc of magnesium sulfate is poured on the cervix again.
Category
Treatment - Drugs

2

Description
Control group:, distilled water is used instead of magnesium sulfate for blinding
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Asalian Hospital
Full name of responsible person
Dr. Masoumeh Ghaffarzadeh
Street address
Palestine Alley, 14 Asalian Hospital
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khorramabad
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Lorestan
Postal code
6818795895
Phone
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Email
asali.hospital@lums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Ebrahim Falahi
Street address
Kamalvand, km 4 of Khorramabad-Borujerd road, medical school
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381351698
Phone
+98 66 3312 0172
Email
Medicine@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

dr.fateme yari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Kamalvand - 4 km of Khorramabad-Borujerd road, medical school

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Ph.D.

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

It is possible to share all the data while maintaining the principle of not mentioning the names of individuals

When the data will become available and for how long

One year after the publication of the related article

To whom data/document is available

Researchers of university centers

Under which criteria data/document could be used

The data of the present study can be used after obtaining permission and approval from the Vice Chancellor for Research and Technology of Lorestan

University of Medical Sciences

From where data/document is obtainable

Refer to the project manager, Dr. Fatemeh Yari, with email address yari1672@yahoo.com, and contact number 09163613621

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

After completing the research and publishing the relevant article, individuals can apply to the Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences to receive documents and after obtaining permission from this department, send a confirmation from the Vice Chancellor for Research to the project manager. Can access documentation.

Comments