

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 66 1222 6450

Email address

yari.f@lums.ac.ir

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 disproportion 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 committee 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

City

khorrabad

Province

Lorestan

Postal code

6818795895

Phone

+98 66 3340 6099

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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khorrabad

Province

Lorestan

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381351698

Phone

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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,
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Person responsible for scientific 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

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Person responsible for updating data

Contact

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Full name of responsible person

fateme yari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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