Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of topical magnesium sulfate on the progression of effacement, dilatation and duration of labor in nullipar women

Protocol summary

Study aim
Determining and comparing the progression of effacement, cervical dilatation and duration of labor in magnesium sulfate group and control before and after the intervention

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 98 pregnant women. Random number table was used for randomization.

Settings and conduct
In this double-blind clinical trial, 98 nulliparous women with term pregnancy referred to Kosar Hospital in Qazvin. Participants were randomly divided into two groups of 49 people. In the intervention group, 10 cc of 50% magnesium sulfate is poured on the cervix from the fingertips of the examiner during vaginal examination so that the whole cervix is covered with it. In the second group, distilled water is used in the same way. In order to blind the participants in the control group, distilled water is used instead of magnesium sulfate.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Mother age between 18 until 35 years; Being primiparous; Full gestational age 37-42 weeks; Live single fetus; Spontaneous start of the labor process
Exclusion criteria: History of infertility; Having risky underlying diseases

Intervention groups
In one group, the whole cervix is impregnated with 50% magnesium sulfate through a 10 cc syringe during vaginal examination, and in the other group, distilled water is used in the same way.

Main outcome variables
Dilatation, effacement, duration of labor

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120428009576N5**
Registration date: **2021-01-18, 1399/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-18, 1399/10/29**
Update count: **0**

Registration date
2021-01-18, 1399/10/29

Registrant information
Name
Ezzatsadat Haji seyed javadi
Name of organization / entity
Qazvin University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 28 3223 6374
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ehajiseyedjavadi@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of topical magnesium sulfate on the progression of effacement, dilatation and duration of labor in nullipar women

Public title
The effect of topical magnesium sulfate on the progression of effacement, dilatation and duration of labor in nullipar women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Mother age between 18 until 35 years Being primiparous Full gestational age 37-42 weeks Live single fetus with head display and estimated weight 2500-4000 grams Spontaneous start of the labor process Body mass index 19.8-30 kg per square meter
Exclusion criteria:
History of infertility Having risky underlying diseases (heart disease, lung disease, connective tissue and smooth muscle problems, and fetal head incompatibility with the mother's pelvis) Fetal heart rate problems Incidence of placental abruption and umbilical cord prolapse Patient non-cooperation
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, randomization was performed using a table of random numbers. First, a number of numbers were randomly placed in the table and specified by the researcher to read the numbers from top to bottom in the table, then even numbers were used for intervention A and odd numbers were used for intervention B.
Blinding (investigator's opinion)
Double blinded
Blinding description
Considering that in the intervention group, 10 cc of 50% magnesium sulfate will be applied topically through the vagina using a syringe, In the control group, under the same conditions, only distilled water will be used instead of magnesium sulfate to blind the researcher and the patient. It should be noted that completely identical vials of distilled water and magnesium sulfate will be used without the drug name label. These vials will be separated by a label containing a code, and 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 Qazvin University of Medical Sciences
Street address
Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd
City
Qazvin
Province
Qazvin
Postal code
3415613911
Approval date
2020-12-26, 1399/10/06
Ethics committee reference number
IR.QUMS.REC.1399.363

Health conditions studied

1

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

Primary outcomes

1

Description
Cervical effacement
Timepoint
At the beginning of the active phase and then every two hours
Method of measurement
Through vaginal examination

2

Description
Cervical dilatation
Timepoint
At the beginning of the active phase and then every two hours
Method of measurement
Through vaginal examination

Secondary outcomes

1

Description

Type of delivery

Timepoint

After delivery

Method of measurement

View and record in the file

2

Description

Duration of labor

Timepoint

Every two hours

Method of measurement

Per second

3

Description

Apgar score

Timepoint

Every two hours

Method of measurement

In terms of score

4

Description

Hemoglobin

Timepoint

Six hours after delivery

Method of measurement

Blood test

5

Description

Postpartum hemorrhage and rupture of the birth canal

Timepoint

After delivery

Method of measurement

Blood tests and examination

Intervention groups

1

Description

Intervention group: In the intervention group, after detecting the active phase with dilation of 3-5 cm, 10 cc of 50% magnesium sulfate made by Shahid Ghazi Pharmaceutical Company of Tabriz-Iran with serial number 3138 is poured on the cervix during vaginal examination, so that the whole cervix is impregnated with it. In addition, in order to better absorb the drug, the mother will be asked to stay in bed for half an hour after taking the drug.

Category

Treatment - Drugs

2

Description

Control group: In the control group, after detecting the active phase with dilation of 3-5 cm, 10 cc of distilled water is poured on the cervix during vaginal examination, so that the whole cervix is impregnated with it. In addition, in order to better absorb the drug, the mother will be asked to stay in bed for half an hour after taking the drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Azin Yazdani

Street address

Kosar Hospital, Taleghani St., Qazvin

City

Qazvin

Province

Qazvin

Postal code

34156-13176

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Email

azin_y6583@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Mohammad Mahdi Emamjomeh

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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

Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Azin Yazdani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Bahonar Blvd, Qazvin
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Person responsible for scientific inquiries

Contact
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Dr Ezzatalsadat Haji Seid Javadi
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Associate Professor
Latest degree
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Person responsible for updating data

Contact
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Latest degree
Medical doctor
Other areas of specialty/work
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Qazvin
Postal code
13176- 34156
Phone
+98 28 3323 6374
Email
azin_y6583@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The collected information is in the form of a questionnaire and is statistically analyzed.
When the data will become available and for how long
The start of the access period is one year after the results are published.
To whom data/document is available
For obstetricians and researchers working in academic institutions
Under which criteria data/document could be used
Evaluate the path and process of study and analyze it
From where data/document is obtainable
For information, refer to Dr. Azin Yazdani. The communication channels are as follows: By sending an email to the address: azin_y6583@yahoo.com or refer and contact Kosar Hospital at the address: Qazvin, Taleghani St. Phone: 028-33236374 Postal address: 34156-13176
What processes are involved for a request to access

data/document

After sending the e-mail, the requested information will be reviewed by the facilitator and the person responsible for the scientific response of the study. At your discretion, the requested information will be sent within 10 days after receiving the email.

Comments