

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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

Email address

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
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Qazvin
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34156-13176
Phone
+98 28 3323 6374
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
Street address
Qazvin
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Postal code
3415613911
Phone
+98 28 3333 6001
Fax
Email
research.dpt@qums.ac.ir
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

Street address

Bahonar Blvd, Qazvin

City

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Qazvin

Postal code

3413786313

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

Qazvin University of Medical Sciences

Full name of responsible person

Dr Ezzatalsadat Haji Seid Javadi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kosar Hospital, Taleghani St., Qazvin

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dr_seidjavadi@yahoo.com

Person responsible for updating data**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

Street address

Kosar Hospital, Taleghani St., Qazvin

City

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Province

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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