

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of topical magnesium sulfate compared with topical normal saline on the cervix in the progression of labor : a randomized clinical trial

Protocol summary

Study aim

Determining the effect of topical magnesium sulfate on the cervix in the progression of labor : A clinical trial

Design

Two arm parallel group randomized trial with 100 pregnant women in each group, randomized with block randomization method

Settings and conduct

This study will be performed in labor ward , Kamali hospital, Karj on all women candidates for normal delivery who are eligible for the study. Patients who have consciously signed a consent form to participate in the project will be randomly assigned to two groups. The randomization list will be prepared by the statistician. Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained. Completing the final information is the responsibility of the person who is unaware of the type of treatment. The statistician will also be kept blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant woman candidate for vaginal birth, primigravida gestational age \geq 38 weeks; Non-inclusion criteria: Indications for cesarean section including failure to progress, cessation of labor, decreased heart rate, bleeding and cleft palate, placenta abruption, fever, and chorioamnionitis, underlying diseases such as diabetes and hypertension, Preeclampsia and eclampsia

Intervention groups

Intervention group: They will received 5 cc magnesium sulfate 50%, topically on the cervix in the latent and active phase of labor. Control group: They will received 5 cc normal saline, topically on the cervix in the latent and active phase of labor

Main outcome variables

Duration of labor, changes in Bishop score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210127050156N2**

Registration date: **2021-12-06, 1400/09/15**

Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**

Update count: **0**

Registration date

2021-12-06, 1400/09/15

Registrant information

Name

Masoumeh Farahani

Name of organization / entity

The Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 5627

Email address

m.farahanii@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of topical magnesium sulfate compared with topical normal saline on the cervix in the progression of labor : a randomized clinical trial

Public title
The effect of topical magnesium sulfate on the cervix in the development of labor

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant woman candidate for vaginal birth primigravid gestational age >= 38 weeks

Exclusion criteria:

Indications for cesarean section include failure to progress, cessation of labor, decreased heart rate, bleeding and cleft palate, placenta abruption , fever, and chorioamnionitis Underlying diseases such as diabetes and hypertension Preeclampsia Eclampsia

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Pregnant women who consented to participate were randomly selected to receive either Magnesium sulfate or Normal Saline . The block randomization method will be designed by using "www.sealedenvelope.com". The size of blocks is 4.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The randomization list will be prepared by the statistician. Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained. Completing the final information is the responsibility of the person who is unaware of the type of treatment. The statistician will also be kept blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

City

Karaj

Province

Tehran

Postal code

3149779453

Approval date

2021-10-25, 1400/08/03

Ethics committee reference number

IR.ABZUMS.REC.1400.199

Health conditions studied

1

Description of health condition studied

labor

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of labor

Timepoint

After delivery

Method of measurement

Stopwatch

2

Description

Bishop Score changes

Timepoint

Every two hours until delivery

Method of measurement

Score Bishop Curve

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will received 5 cc magnesium sulfate 50%, topically on the cervix in the latent and also in the active phase of labor

Category

Treatment - Drugs

2

Description

Control group: They will received 5 cc normal saline, topically on the cervix in the latent and also in the active phase of labor

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Masoumeh Farahani

Street address

Kamali hospital; Kamali alley; Shohada square;
Shahid Beheshti street

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Email

m.farahanii@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

Street address

Vice Chancellor for Research; No.20; Saffarian alley;
45 Metri Golshahr street

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3198764653

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Masoumeh Farahani

Position

Professor assistant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

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