

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effects of topical magnesium sulfate on the active phase and progression of labor in nulliparous women

Protocol summary

Study aim

Evaluating the effects of topical magnesium sulfate on the active phase and progression of labor in nulliparous women

Design

A controlled clinical trial with randomized double-blind randomized parallel groups is performed on 74 patients.

Settings and conduct

Study place is Kamali educational clinical center .In order to prepare patient's randomly allocated successions, it was placed in sealed envelopes that are designated in 5 digit serial numbers, by a third person who is not involved in the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pregnant women with gestational age of 37 to 42 weeks first labor single fetus weighting between 3.5 - 4 kg low risk, non-induced labor BMI of the mother being between 19.8 and 30 kg/m² exclusion criteria: any sign indicating fetal heart rate abnormalities, placenta abruption, cord prolapse or anything that pregnancy is high risk cephalopelvic disproportion mothers' chronic underlying disease like anemia, hemophilia, cardiopulmonary or neuromuscular disease any sign of allergy or toxicity caused by magnesium sulfate

Intervention groups

Intervention group: 10 cc of 50% topical magnesium sulfate solution is poured by a 10 cc syringe through the fingers and completely covers the cervix. Control group: Control group which does not receive magnesium sulfate, their data is collected for comparison with the intervention group.

Main outcome variables

Fetal station-Cervical dilation-Cervical effacement-Cervical consistency-Cervical position-Bishop score-length of the active phase of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201024049128N3**

Registration date: **2021-08-09, 1400/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-09, 1400/05/18**

Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Bita Badehnoosh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3222 2021

Email address

badehnoosh@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of topical magnesium sulfate on the active phase and progression of labor in nulliparous women

Public title

Effects of topical magnesium sulfate on progression of labor

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women with gestational age of 37 to 42 weeks
First labor Single fetus weighting between 3.5 - 4 kg Low risk, non-induced labor BMI of the mother being between 19.8 and 30 kg/m²

Exclusion criteria:

Any sign indicating fetal heart rate abnormalities, placenta abruption, cord prolapse or anything that pregnancy is high risk Cephalopelvic disproportion Mothers' chronic underlying disease like anemia, hemophilia, cardiopulmonary or neuromuscular disease Any sign of allergy or toxicity caused by magnesium sulfate

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are recruited in from referred clientele of Kamali hospital that have inclusion criteria. 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 control group. This randomization are done with Random number generator command of STATA software until reaching determined sample size . In this special randomized study people are categorized in control and study group with technique of Balanced block randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to prepare patient's randomly allocated successions, it was placed in sealed envelopes that are designated in 5 digit serial numbers, by a third person who is not involved in the trial. All the envelopes carry

this 5 digit serial number and are opened immediately after completion of patient's work-up and basic lab tests and thus categorize them into intervention and control groups. No patient is aware of another's progression or outcome.

Placebo

Not 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

Research and Development Department of Alborz University of Medical Sciences, Safarian Ave, 45 Metri Blvd, Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2021-03-08, 1399/12/18

Ethics committee reference number

IR.ABZUMS.REC.1400.004

Health conditions studied**1****Description of health condition studied**

Active phase and progression of Labor in nulliparous women

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fetal station

Timepoint

Every 2 hours until the end of active phase of labor

Method of measurement

Physical examination and recording the data on questionnaire

2

Description

Cervical dilation

Timepoint

Every 2 hours until the end of active phase of labor

Method of measurement

Physical examination and recording the data on questionnaire

3

Description

Cervical effacement

Timepoint

Every 2 hours until the end of active phase of labor

Method of measurement

Physical examination and recording the data on questionnaire

4

Description

Cervical consistency

Timepoint

Every 2 hours until the end of active phase of labor

Method of measurement

Physical examination and recording the data on questionnaire

5

Description

Cervical position

Timepoint

Every 2 hours until the end of active phase of labor

Method of measurement

Physical examination and recording the data on questionnaire

6

Description

Bishop score

Timepoint

Every 2 hours until the end of active phase of labor

Method of measurement

Calculated by adding up the scores of the first 5 variables, maximum score of 15

7

Description

Length of the active phase of labor

Timepoint

Every 2 hours until the end of active phase of labor

Method of measurement

Physical examination and recording the data on questionnaire

Secondary outcomes

empty

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 Bishop 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 on the cervix again. Generic drug used is magnesium sulfate injection parenteral 10 % 50milliliter (infu-magnesol); made by shahid ghazi pharmaceuticals company; IRC 6210969267810048.

Category

Treatment - Drugs

2

Description

Control group : we perform no special intervention on them just measure the above mentioned factors without magnesium sulphate. Then the data are comprised with the data of intervention group after entering in the analyzing program.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Bita Badehnoosh

Street address

Kamali Hospital; Kamali Alley; Shohada Square; Shahid Beheshti Street

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3149779453

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Research@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

Street address

Vice Chancellor for Research; No.20; Saffarian alley;
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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

Alborz 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**

Alborz University of Medical Science

Full name of responsible person

Reza Rakhshafar

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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

Alborz University of Medical Sciences

Full name of responsible person

Bita Badehnoosh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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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