Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 of15

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 intevention 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Mohammad Nourisepehr

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Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
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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
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Medical Education
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Person responsible for scientific inquiries

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Assistant Professor
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Specialist
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Gynecology and Obstetrics
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Person responsible for updating data

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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