Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effects of topical magnesium sulfate on duration of labor and childbirth experience: a randomized controlled trial

Protocol summary

Study aim
To determine effect of topical magnesium sulfate on the duration of labor and childbirth experience in term pregnancy

Design
Randomized superiority placebo-controlled double-blind trial with two parallel arms on 98 women hospitalized for vaginal delivery. The randomizer software will be used for randomization.

Settings and conduct
In Taleghani teaching hospital in Tabriz-Iran, eligible women hospitalized for vaginal delivery will be randomized into one of the two study groups using stratified block randomization, after receiving informed written consent. They will be continuously monitored until delivery and followed up until one month after delivery. The drug and placebo will be identical in appearance. Participants, those recruiting and allocating participants, intervener, and data collector and analyzer will be blinded.

Participants/Inclusion and exclusion criteria
Participants will be nulliparous or women with a 1-2 parity, aged 18-35 years and body mass index 19.8-30 kg/m2, without a history of cesarean section, with alive cephalic single mature fetus with estimated weight 2500 to 4000 g. Other inclusion criteria include low risk pregnancy, spontaneous or non-spontaneous onset of labor, 40-70% cervical effacement, station -2 to 0, and woman adequate literacy. Exclusion criteria include: history of infertility, risky diseases, normal delivery contraindications (including cepholo-pelvic disproportion), fetal heart rate disorders before intervention, and unwillingness to participate in the study.

Intervention groups
Intervention group: receiving 10 mL of magnesium sulfate 50% intravaginally. Control group: receiving 10 mL of distilled water intravaginally.

Main outcome variables
The interval between intervention initiation and vaginal delivery; Score of childbirth experience

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100414003706N40**
Registration date: **2021-11-21, 1400/08/30**
Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**
Update count: **0**

Registration date
2021-11-21, 1400/08/30

Registrant information

Name
Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3477 2699

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-10, 1400/09/19

Expected recruitment end date
2022-05-09, 1401/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of topical magnesium sulfate on duration of labor and childbirth experience: a randomized controlled trial

Public title
Comparison of effect of topical magnesium sulfate and placebo (distilled water) on duration of labor and childbirth experience

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 18-35 years, nulliparoue or with 1-2 parous without a history of cesarean section Body mass index 19.8-30 kg/m2 (based on weight of pre-pregnancy or first trimester of pregnancy) A live singleton term fetus (gestational age of 37-41 weeks) in estimated weight 2500 to 4000 g and cephalic presentation Having sufficient literacy to read and understand study questionnaires Spontaneous or non-spontaneous onset of labor process Cervical effacement 40-70% Station -2 to 0

Exclusion criteria:
History of infertility Contraindications to vaginal delivery including placental abruption, umbilical cord prolapse, cephalopelvic disproportion (CPD) Fetal heart rate disorders in the pre-intervention stage High risk pregnancy (bleeding in the third trimester, placental abruption, placenta previa, fetal growth disorder, etc.) Risky diseases (such as severe anemia (hemoglobin less than 7 g/dL) or blood disorders, heart disease, lung disease, connective tissue and smooth muscle problems) Unwillingness to participate in the study

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation sequence will be generated using stratified block randomization (stratified by previous history of labor and type of labor onset (spontaneous or induction)) with block size of four and allocation ration 1:1 using a computerized program (Randomizer). Sequentially numbered opaque sealed envelopes including syringe containing the drug or placebo will be used to conceal the allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
Syringes containing 10 mL magnesium sulfate or distilled water (identical in appearance) will be packed in sequentially numbered opaque sealed envelopes. The preparation of the envelopes will be performed by a person non-involved in participant recruitment and data collection. The participants, those involved in the recruitment, allocation and data collection, also analyzer will not be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-10-25, 1400/08/03

Ethics committee reference number
IR.TBZMED.REC.1400.726

Health conditions studied

1

Description of health condition studied
Prolonged labor

ICD-10 code
O63.0

ICD-10 code description
Prolonged first stage (of labor)

Primary outcomes

1

Description
The interval between intervention initiation and childbirth

Timepoint
After delivery

Method of measurement
Timer

2

Description
Score of maternal birth experience
Timepoint
One month after delivery
Method of measurement
Childbirth Experience Questionnaire 2.0

Secondary outcomes

1

Description
Score of birth satisfaction
Timepoint
12-24 h after childbirth
Method of measurement
Birth satisfaction scale-revised questionnaire

2

Description
Pain intensity
Timepoint
About 30 min before the intervention and then 1, 2 and 3 h after starting the intervention
Method of measurement
Visual Analog Scale

3

Description
Duration of the second stage of labor
Timepoint
After fetal expulsion
Method of measurement
Timer

4

Description
Duration of the third stage of labor
Timepoint
After complete expulsion of the placenta
Method of measurement
Timer

5

Description
Bishop Score
Timepoint
Just before the intervention and 2 h after starting the intervention
Method of measurement
Bishop Scoring Table

6

Description
Hemoglobin and hematocrit
Timepoint
12- 24 h after delivery
Method of measurement
Laboratory test

7

Description
Childbirth fear
Timepoint
At baseline and two h after starting intervention
Method of measurement
Delivery Fear Scale

8

Description
Severity of postpartum fear
Timepoint
12-24 h and one Month after delivery
Method of measurement
Wijma Version B scale

Intervention groups

1

Description
Intervention group: Just after onset of active phase of labor (cervical dilation of 4-5 cm with regular uterine contractions), 10 mL of magnesium sulfate 50% made by Yara Teb Samen Pharmaceutical Company will be poured on the cervix through a 10 mL syringe during vaginal examination from the fingertips of the examiner, so that the whole cervix is impregnated with it. To better absorption of the drug, the women will be asked to sleep in bed for at least half an hour after pouring the drug. If the amniotic sac ruptures less than half an hour after pouring the drug, another 10 mL of magnesium sulfate will be poured on the cervix after discontinuing the discharge.
Category
Treatment - Drugs

2

Description
Control group: Just after onset active phase of labor (cervical dilation of 4-5 cm with regular uterine contractions), 10 mL of placebo (distilled water) will be poured on the cervix through a 10 mL syringe during vaginal examination from the fingertips of the examiner, so that the whole cervix is impregnated with it. The women will be asked to sleep in bed for at least half an hour after pouring the placebo. If the amniotic sac ruptures less than half an hour after pouring the placebo, another 10 mL of distilled water will be poured on the cervix after discontinuing the discharge.
Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani Medical Research & Training Hospital
Full name of responsible person
Mansour Rezaei
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Parviz Shahabi
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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
Tabriz 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
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Sahar Ruhzendeh
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All deidentified IPD can be shared.

When the data will become available and for how long
Starting soon after publication of the study results.

To whom data/document is available
Data will be available for researchers working in academic institutions, as well as to chief editor and reviewers of the submitted manuscript.

Under which criteria data/document could be used
The data will be available to researchers upon request and submission of the proposal to perform meta-analysis using IPD. Also, in exceptional cases, data will be made available to chief-editor of the journals for checking.

From where data/document is obtainable
Refer to the email addresses (alizades@tbzmed.ac.ir).

What processes are involved for a request to access data/document
The requests should be sent by email and data will be available within two week.

Comments