Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Intravaginal Magnesium Sulfate vs Intravenous Dexamethasone for Labor Acceleration: A Bayesian Adaptive Randomized Controlled Trial

Protocol summary

Study aim

Investigating the effect of vaginal magnesium sulfate on labor progress compared to intravenous dexamethasone in primiparous pregnant women

Design

A randomized, adaptive, parallel-group, phase 3 clinical trial with three arms (magnesium sulfate vaginal, intravenous dexamethasone, and routine care control), blinded outcome assessment, and interim analysis. The trial will enroll 150 patients initially, with potential sample size adjustment via Bayesian simulation. Randomization will use block allocation (block sizes of 3, 6, 12) generated via sealedenvelope.com, with allocation concealment maintained through sequentially numbered opaque envelopes.

Settings and conduct

Maternity ward of Kamali Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant woman candidate for vaginal birth, primigravida gestational age>= 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: receiving 10 cc of magnesium sulfate 50% topically on the cervix once in the latent phase and once in the active phase of labor. - Comparison group 50 people in the comparison group will be given 2 cc (8 grams) of intravenous dexamethasone

Main outcome variables

Duration of labor, changes in Bishop's score and reduction of labor pain Reduce bleeding

General information

Reason for update

Request to Change Study Type in the IRCT System Respectfully, we request a modification of the study type from "Traditional Randomized Clinical Trial" to "Adaptive Clinical Trial (Bayesian Approach)" in the IRCT system. The key changes are as follows: Key Modifications: Study Type: Revised to: "A three-arm Bayesian adaptive clinical trial, including an interim analysis after collecting data from 50 patients in each group. If equivalence or superiority of magnesium sulfate (posterior probability ≥85%) is confirmed, the dexamethasone arm will be discontinued, and allocation will continue between the magnesium sulfate and control groups." Data Analysis Method: Revised to: "Bayesian analysis using non-informative prior distributions, calculation of the probability of superiority, and reporting results with a Bayesian credible interval." Ethical Considerations: Added: Revised informed consent to inform patients about the possible discontinuation of the dexamethasone arm. Establishment of an independent Data and Safety Monitoring Board (DSMB) for safety oversight and interim analysis. Scientific and Ethical Justifications for the Changes: Limited Evidence: No direct comparison between magnesium sulfate and dexamethasone exists in previous studies. Resource Optimization: Preventing sample wastage by discontinuing the non-optimal arm (dexamethasone) if magnesium sulfate proves superior. Safety Considerations: Reducing patient exposure to dexamethasone side effects (e.g., increased blood pressure, immune suppression).

Acronym

IRCT registration information

IRCT registration number: **IRCT20230823059227N2**
Registration date: **2024-07-30, 1403/05/09**
Registration timing: **prospective**

Last update: **2025-11-25, 1404/09/04**
Update count: **2**

Registration date

2024-07-30, 1403/05/09

Registrant information

Name
Kobra Hosseini
Name of organization / entity
Alborz University of medical science
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-08-21, 1403/05/31
Expected recruitment end date
2025-08-20, 1404/05/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Intravaginal Magnesium Sulfate vs Intravenous Dexamethasone for Labor Acceleration: A Bayesian Adaptive Randomized Controlled Trial

Public title
Effect of magnesium sulfate on reducing the duration and pain of labor
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant woman candidate for vaginal birth Low risk of pregnancy Live singleton fetus Gestational age of 38 weeks and above Bishop score less than 4
Exclusion criteria:
History of infertility Having dangerous underlying diseases failure to progress bradycardia History of uterine scar
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
After the eligibility of the patient was recognized and written informed consent was obtained, the patients were randomly assigned to one of the three intervention (magnesium sulfate) and comparison (intravenous dexamethasone) and control (routine treatment) will be allocated. A randomization list is prepared. To prepare the randomization list, from the web-based software to the address https://www.sealedenvelope.com/simple-randomiser/v1/lists will be used.
Blinding (investigator's opinion)
Triple blinded
Blinding description
It is not possible to blind the patient. The researcher investigating the outcome and analyzing the data: He is not aware of the patient's randomization group and he is the only researcher who randomly selected the list. He is aware of this matter
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 Science
Street address
Alborz University of Medical Science, Official settlement, North Taleghani boulevard, Taleghani Square, Karaj, Alborz Province
City
Karaj
Province
Alborz
Postal code
3147734568
Approval date
2024-06-08, 1403/03/19
Ethics committee reference number
IR.ABZUMS.REC.1403.076

Health conditions studied

1

Description of health condition studied
Prolonged first stage (of labor)
ICD-10 code
O63.0
ICD-10 code description
Prolonged first stage (of labor)

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

1

Description
Changes in neonatal blood glucose level
Timepoint
The first 2 hours after delivery.
Method of measurement
Newborn blood sugar measurement with a glucometer in the first 2 hours after delivery.

Intervention groups

1

Description
The intravenous dexamethasone group. 50 people in the intravenous dexamethasone group (8 mg or 2 cc of intravenous dexamethasone diluted with distilled water and injected intravenously during the active phase of slow labor) .
Category
Treatment - Drugs

2

Description
Vaginal magnesium sulfate group. 50 people in the vaginal magnesium sulfate group (10 cc of 50% magnesium sulfate, which is poured directly on the client's cervix during the active phase of labor
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali Hospital
Full name of responsible person
Mina Ataee
Street address
Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street
City
Alborz
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3149779453
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Kobra.hosseini1990@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Razieh Lotfi
Street address
KAMALI Hospital, Kamali alley, Shahid Beheshti st, Shohada Squ,
City
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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
Karaj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Kobra Hosseini
Position
Medical Intern
Latest degree
Medical doctor
Other areas of specialty/work
Obstetrics and Gynecology
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Latest degree
Medical doctor
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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