Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of local magnesium sulfate on the progression of effacement, dilatation, process and delivery outcomes in nulipar women

Protocol summary

Study aim

1. Determine and compare the amount of effacement and dilatation of the cervix in the magnesium sulfate group and control before intervention. 2. Determining and comparing the amount of effacement and dilatation of cervix in magnesium sulfate group and control after intervention 3. Determination and comparison of cesarean delivery in magnesium sulfate and control group 4 Determine and compare the degree of rupture of grade 3 and 4 in magnesium sulfate and control group 5. Determination and comparison of postpartum hemoglobin and hematocrit changes in magnesium sulfate and control group 6 Determine and compare the duration of labor in the magnesium sulfate and control group 7. Determine and compare apgar score 1 and 5 neonates in magnesium sulfate and control group

Design

In this study, 72 nulipar pregnant women who are referred to the Mahdieh hospital for admission to delivery and have incloud criteri to the study are examined. Contributors will be placed in control or intervention groups according to the randomized random numbers table. Treatment groups are identified by codes A and B, and each participant is assigned a code.

Settings and conduct

This is a triple blind clinical trial performed at Shahid Beheshti University of Medical Sciences in Mahdieh Hospital. The method of blindness, drug use or placebo is performed by the researcher and follow-up is done by the research fellow. Fellow researchers and patients are unaware of the treatment group. After the completion of the data, the data is analyzed by the spss software, the analyst is also unaware of the treatment groups

Participants/Inclusion and exclusion criteria

Incloud criteria; nuliparous, gestational age 37-42 weeks, age 18-35 years, single and live fetus, cefalic presntation; Conditions of failure to enter: having chronic, risky illness CPD disorder Estimated baby weight more than 4000 grams or less than 2500 grams High risk pregnancy Having history of infertility

Intervention groups

After giving explanations to the samples, they are informed consent. In the active phase, 10 cc magnesium sulfate 50% will be deposited on the uterine cervix and in the control group 10 cc of distilled water will be used, and then the delivery process and its consequences including delivery type, newborn Apgar score and rate Blood and laceration in the delivery canal be measured and compared in both the control and intervention groups.

Main outcome variables

The type of delivery, the amount of bleeding, the length of delivery and the Apgar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170121032085N1**
Registration date: **2017-12-03, 1396/09/12**
Registration timing: **retrospective**

Last update: **2017-12-03, 1396/09/12**
Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

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Arezoo Heydari
Name of organization / entity
shahid Beheshti Medical university
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Recruitment status
Recruitment complete
Funding source
Deputy of Research of Shahid Beheshti Nursing Faculty

Expected recruitment start date
2017-02-26, 1395/12/08
Expected recruitment end date
2017-10-02, 1396/07/10
Actual recruitment start date
2017-02-26, 1395/12/08
Actual recruitment end date
2017-10-02, 1396/07/10
Trial completion date
empty

Scientific title
The effect of local magnesium sulfate on the progression of effacement, dilatation, process and delivery outcomes in nulipar women

Public title
The effect of local magnesium sulfate on the progression of effacement, dilatation, process and delivery outcomes
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
All nulipar pregnant women Gestational age 37-42 weeks 18-35 years old Live and single fetus cefalic presentasion
Exclusion criteria:
Having chronic, risky illness CPD disorder Estimated baby weight more than 4000 grams or less than 2500 grams High risk pregnancy Having history of infertility
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
Actual sample size reached: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done using random numbers tabel . For the control and intervention group, codes A and B were used as contractions. Then, before the intervention, using Excel software, a randomized table for the order of sampling was prepared.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Before starting the intervention, all the specimens needed explanations, but the samples were not known to be in the intervention or control group. The drug or placebo was prescribed by the investigator, but the assistant in the study who performed the examinations with him from the treatment group was unaware. The attending physician was aware of the patient's treatment group, but the person analyzing the statistical information from the treatment group was unaware.
Placebo
Used
Assignment
Parallel
Other design features
There is no other explanation.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti university of Medical science
Street address
Tehran, Valiasr St., in front of Shahid Rajaee Heart Hospital, Faculty of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2016-07-18, 1395/04/28
Ethics committee reference number
IR.SBMU.PHNM.1395.493

Health conditions studied

1

Description of health condition studied
labor progress
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
During the active phase of labor
Timepoint
During the intervention
Method of measurement
Vaginal examination

2

Description
type of delivery
Timepoint
at the birth
Method of measurement
questionnaire

3

Description
Apgar scores in minutes 1 and 5
Timepoint
1 and 5 minute after delivery
Method of measurement
observe

Secondary outcomes

1

Description
Postpartum haemorrhage and laceration of the delivery channel
Timepoint
After delivery and intervention
Method of measurement
Blood testing and inspection

Intervention groups

1

Description
In the intervention group in the active phase of labor, 10 cc magnesium sulfate is shed 50% on the uterine cavity. If within 2 hours after examination of the uterine cavity, the other 10 cc magnesium sulfate 50% on the uterine crater Shed
Category
Treatment - Drugs

2

Description
In the control group, in the active phase of labor, 10 cc of water is excreted in the uterine cavity. If, during the next 2 hours, the condition of the uterine cavity has not changed in the examination, once again 10 cc of mucosal sulfate is poured over t
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Hospita
Full name of responsible person
Arezoo Heydari
Street address
Tehran - Vali Asr street-before Niayesh prayer-school of shahid Beheshti Nursing- Midwifery
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, shahid beheshty University of Medical Sciences
Full name of responsible person
mahrokh dolatian
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tehran. shahid beheshty medical university. midwifery department
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Grant name
0
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, shahid beheshty University of Medical Sciences
Proportion provided by this source
20
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
Shahid Beheshti university of medcal science

Full name of responsible person
Arezoo Heydari

Position
Post graduate Midwifery student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
To keep confidential secrets of contributors

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