

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 Mahdiah hospital for admission to delivery and have included criteria 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 Mahdiah 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

Inclusion criteria; nuliparous, gestational age 37-42 weeks, age 18-35 years, single and live fetus, cephalic presentation; 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

Name

Arezo Heydari

Name of organization / entity

shahid Beheshti Medical university

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 9750

Email address

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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

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget 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 Rajaei 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 medical science

Full name of responsible person

Arezo Heydari

Position

Post graduate Midwifery student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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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