Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effect of intravaginal application of magnesium sulfate on the intensity of labor pain, and the duration of the t first and second stages of labor in nulliparous women referred to Al-zahra hospital: A Clinical Trial

Protocol summary

Study aim
Effect of intravaginal application of magnesium sulfate on the intensity of labor pain, and the duration of the t first and second stages of labor in nulliparous women referred to Al-zahra hospital: A Clinical Trial

Design
Clinical trial with control group, with parallel groups, double blind, randomized

Settings and conduct
Location: Guilan university of medical sciences, Al-Zahra hospital, gynecology clinic. 72 eligible patients will be included in this study.

Participants/Inclusion and exclusion criteria
Inclusion criterias: Nullipara women in the active phase of labor ,not being prom ,not using calcium blocker drugs ,woman between age 18-35, prime para, single tone cephalic fetus ,estimated fetal weight between 2500-4000 gr, low risk pregnancy .BMI 19.8-30,no drug abuse. Exclusion criterias: Infertility history, history of dangerous underlying disease,History of drug use during pregnancy, Polyhydramnios, Participate in childbirth preparation classes during pregnancy and the presence of any contraindications to natural childbirth.

Intervention groups
Intervention group: group A, after vaginal examination 10cc of magnesium sulfate 50% will be applied intravaginally on the cervix at the dilatations of 5-6cm,7-8cm 9-10 cm .group B will receive placebo (in the same size and shape) in the same way as group A.

Main outcome variables
Factors examined include intensity of pain in dilatation of 3-5 cm 7-8 cm 09-10 cm of cervix

General information

Reason for update

Acronym
magnesium sulfate

IRCT registration information
IRCT registration number: **IRCT20200510047377N1**
Registration date: **2020-06-18, 1399/03/29**
Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**
Update count: **0**

Registration date
2020-06-18, 1399/03/29

Registrant information

Name
Fereshteh Fakoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3336 9224

Email address
fereshtehfakor@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-24, 1399/04/04

Expected recruitment end date
2021-01-23, 1399/11/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of intravaginal application of magnesium sulfate

on the intensity of labor pain, and the duration of the t first and second stages of labor in nulliparous women referred to Al-zahra hospital: A Clinical Trial

Public title
Effect of intravaginal application of magnesium sulfate on the intensity of labor pain, and the duration of the t first and second stages of labor in nulliparous women referred to Al-zahra hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Nullipara women in the active phase of labor Not being PROM Woman between age 18-35, Prime para Single tone cephalic fetus Estimated fetal weight between 2500-4000 gr Low risk pregnancy BMI 19.8 - 30 Not using calcium blocker drugs No drug abuse Pregnancy age 37 to 42 weeks

Exclusion criteria:
Infertility history History of dangerous underlying disease History of drug use during pregnancy Polyhydramnios Participate in childbirth preparation classes during pregnancy The presence of any contraindications to natural childbirth

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Initially, patients receive a written consent form and execution methods and interventions are explained. Then eligible people,They are randomly assigned to two groups by the method of 4 random blocks.These patients are divided into two groups treated with magnesium sulfate the control group. None of the participants in the study will be notified of the randomization list .for concealment practices we use sealed envelopes that are numbered in order And the envelope for each person only after Confirmation of the eligibility criteria for her to enter the study and Signing the consent ,will be opened. Register and randomization will be done by third person.

Blinding (investigator's opinion)
Double blinded

Blinding description
After generating the list, each person is assigned a unique code and during the study the person will be identified with this code. None of the participants in the study will be aware of the randomization list and also to apply allocation concealment randomization, the groups are placed in closed envelopes in the admission section and eligible individuals who enter the study are included respectively.Therefore, the study was double-blind so that patients and outcome evaluation specialist are unaware of the allocation status of the two groups to the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave., Rasht, Guilan, IRAN

City
Rasht

Province
Guilan

Postal code
41446-66949

Approval date
2020-05-27, 1399/03/07

Ethics committee reference number
IR.GUMS.REC.1399.087

Health conditions studied

1

Description of health condition studied
labor facilitation

ICD-10 code
O00-O99

ICD-10 code description
ICD-10 Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
The intensity of pain in dilatation is 3-5 cm

Timepoint
The time interval between entering the labor and reaching the dilatation 3-5 cm of the cervix

Method of measurement
visual analogue scale

Secondary outcomes

1

Description
The intensity of pain in dilatation is 3-5 cm
Timepoint
The time interval between entering the labor and reaching the dilatation 3-5 cm of the cervix
Method of measurement
visual analogue scale

2

Description
The intensity of pain in dilatation is 7-8 cm
Timepoint
time interval 3-5 until the examination of the cervix 7-8 cm
Method of measurement
visual analogue scale

3

Description
The intensity of pain in dilatation is 9-10 cm
Timepoint
time interval 7-8 until the examination of the cervix 9-10 cm
Method of measurement
visual analogue scale

Intervention groups

1

Description
Intervention group:group A, after vaginal examination 10cc of magnesium sulfate 50% will be applied intravaginal on the cervix at the dilatations of 5-6cm,7-8cm 9-10 cm .
Category
Treatment - Drugs

2

Description
Control group: group B will receive normal saline (in the same size and shape) in the same way as group A.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Dr.Fereshteh Fakoor
Street address
Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Fatemeh Gholamalipour
Street address
Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Fatemeh Gholamalipour
Position
Resident of gynocologist Professor
Latest degree

Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position
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Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

Contact

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Seyedeh Maryam Attari

Position
MS of midwifery

Latest degree
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Other areas of specialty/work
Gynecology and Obstetrics

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

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
There are no plans to share and publish it, yet

When the data will become available and for how long
The beginning of the access period is 6 months after the publication of the study results.

To whom data/document is available
All interested in study

Under which criteria data/document could be used
All interested in study

From where data/document is obtainable
by Email

What processes are involved for a request to access data/document
Not yet planned for it.

Comments