Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of magnesium sulfate and nifedipine in treatment of preterm labor in pregnant women with 28-34 weeks of gestational age.

Protocol summary

Study aim
Comparison of nifedipine and magnesium sulfate in the treatment of preterm labor

Design
Clinical trial with two intervention groups, double-blind, randomized, phase 2 on 100 pregnant women with a gestational age of 28-34 weeks and with preterm labor pain

Settings and conduct
The study site was the maternity ward of Imam Khomeini Hospital in Ahvaz. Blinding has been of the double-blind type. In this study for blinding, one group receives nifedipine in addition to oral Ringer serum and one group receives magnesium sulfate in addition to placebo, and thus the patient and the doctor and the treatment staff of the patients do not know which participant belongs to which group.

Participants/Inclusion and exclusion criteria
Inclusion criterion: Single pregnancy with a gestational age of 28 to 34 weeks in the latent phase of labor
Exclusion criterion: Any situation that is inconsistent with continuing the pregnancy and receiving medication

Intervention groups
Intervention group 1: receiving nifedipine with a sample size of 50 people. Intervention group 2: receiving magnesium sulfate with a sample size of 50 people

Main outcome variables
Delaying delivery time with minimal side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201017049052N1**
Registration date: **2020-11-23, 1399/09/03**
Registration timing: **retrospective**
Last update: **2020-11-23, 1399/09/03**
Update count: **0**

Registration date
2020-11-23, 1399/09/03

Registrant information

Name
Mina Mahdavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3337 6318

Email address
mina.m349@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-01, 1398/03/11

Expected recruitment end date
2020-03-18, 1398/12/28

Actual recruitment start date
2019-04-21, 1398/02/01

Actual recruitment end date
2020-03-18, 1398/12/28

Trial completion date
2020-03-18, 1398/12/28

Scientific title
Comparison of magnesium sulfate and nifedipine in treatment of preterm labor in pregnant women with 28-34 weeks of gestational age.

Public title
Effect of magnesium sulfate and nifedipine in preterm labor

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Single fetus pregnancy Pregnancy in 28_34 weeks of gestational age Not in the active phase of labor No contraindication to continue pregnancy
Exclusion criteria:
Any situation that makes it impossible to continue the pregnancy Contraindications to the use of Nifedipin or Magnesium sulfate in the patient

Age
No age limit
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Restricted randomisation of the random allocation role type, This method represents a large block for the entire sample size, This means that a balance in the number of people assigned to each group will be achieved at the end of the study. For this purpose, it first determines a total sample size and then randomly assigns a set of them to group A and the remainder to group B.This method is used for two or more group trials.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blindness, the nifedipine group received Ringer serum in addition to oral medication and the magnesium sulfate group received oral placebo in addition to the injectable drug, and thus the patient, physician, and treatment staff of the patients under study have no knowledge of allocation of individuals to the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Unit 10, Tara Building, No 75, Second Phase, 2nd West St., Kianpars
City
Ahvaz
Province
Khouzestan
Postal code
61558-19619
Approval date
2019-05-31, 1398/03/10
Ethics committee reference number
IR.AJUMS.REC.1398.186

Health conditions studied

1

Description of health condition studied
Preterm Labor
ICD-10 code
O60.00
ICD-10 code description
Preterm labor without delivery, unspecified trimester

Primary outcomes

1

Description
Delaying preterm delivery for more than 48 hours
Timepoint
Measurement of dilatation and effaceman of the cervix before treatment and 24 hours and 48 hours after treatment
Method of measurement
Manual vaginal examination

Secondary outcomes

1

Description
Drug side effects
Timepoint
Frequently after starting treatment until the end of the dose
Method of measurement
Patient statement and questionnaire

Intervention groups

1

Description
Intervention group 1: Nifidipine recipient with an initial dose of 20 mg orally and then every 6 hours for 24 hours
Category
Treatment - Drugs

2

Description

Intervention group 2: Recipient of 20% magnesium sulfate with an initial dose of 4 gram intravenously and then 2 gram per hour for 24 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Ahvaz

Full name of responsible person

Mina Mahdavi

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Unit 10, Tara Building, No 75, Second Phase, 2nd West St., Kianpars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mina Mahdavi

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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

Title and more details about the data/document
All data of study participants can be shared after making people and the entire study protocol unidentifiable.

When the data will become available and for how long
After publishing the results under the title of dissertation and also after registering in the Behsan system of Ahvaz Jundishapur University of Medical Sciences

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The use of all study materials without mentioning the source is unrestricted.

From where data/document is obtainable
Central Library of Ahvaz Jundishapur University of Medical Sciences WWW.centrallib.ajums.ac.ir

What processes are involved for a request to access data/document
Access to the dissertation section is easily possible through the Central Library website.

Comments