

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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Unit 10, Tara Building, No 75, Second Phase, 2nd

West St., Kianpars

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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 effacement 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: Nifedipine 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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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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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.centllib.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