

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of Nifedipin and magnesium sulfate effect on inhibition of preterm labor

#### Protocol summary

##### Summary

This is a randomized single-blind and two centers clinical trial. The aim of this study is to compare the effect of Nifedipin and magnesium sulfate on labor pain. Our sample size is 200 who are enrolled in the study based on inclusion criteria including singleton pregnancy, gestational age 32-34 weeks, 30 second contractions and one contraction in 10 minutes at least. Exclusion criteria include Underlying medical condition, severe preeclampsia, intrauterine infections and congenital anomalies. Patients are randomly allocated into 2 groups. Before treatment both groups are hydrated with 1 liter Ringer serum. In the first group 4 grams magnesium sulfate in 200 cc Ringer serum is infused during 20 minutes and then 2 grams magnesium sulfate is infused per hour and continued up to 24 hours or 2 hours after contraction. Urine volume, respiration rate and patellar reflex are assessed every 4 hours during infusion. In second group, 10 mg oral Nifedipin is administered and if contractions continue for 15 minutes, the second dose is administered and continued every quarter of an hour for 1 hour. Then a 10 mg Nifedipin capsule per 6 hours is administered and continued to 24 hours. Then, the amount of uterine contractions is compared in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016120711020N8**

Registration date: **2017-02-25, 1395/12/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-02-25, 1395/12/07

#### Registrant information

##### Name

Maryam Khoshideh

##### Name of organization / entity

Tehran University of Medical Sciences, Arash Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7788 0909

##### Email address

khooshide@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Zahedan University of Medical Science

#### Expected recruitment start date

2014-10-23, 1393/08/01

#### Expected recruitment end date

2017-02-19, 1395/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of Nifedipin and magnesium sulfate effect on inhibition of preterm labor

#### Public title

Effect of Nifedipin and magnesium sulfate on preterm labor

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Singleton pregnancy; gestational age 32-34 weeks; 30 second contractions and one contraction in 10 minutes at least ; intact amniotic sack; cervical dilatation 2 cm Exclusion criteria: Underlying

medical condition; severe preeclampsia; intrauterine infections; congenital anomalies

#### Age

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

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **200**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Random allocation was performed by a methodologist using Stata V.13 in 6-piece blocks. The code of medicines were placed in similar packets and the sequence of medicines and list of random allocation of patients were not disclosed to dispensing practitioners. To conceal the random allocation process, a random 10-digit code corresponding to the identification number of the patient was written on each packet. These packets were given to the dispensing nurse, who was unaware of the contents of each packet. When the gynecologist declared the eligibility of patients, the nurse gave packets to her according to the identification numbering. The person who assessment outcomes is unaware of the process of random allocation and type of treatment. Because of difference type of drugs administration, participants will not be unaware of kind of treatments so this study is single blind.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zahedan University of Medical Science

##### Street address

Khlije Fars boulevard, Zahedan

##### City

Zahedan

##### Postal code

#### Approval date

2007-01-02, 1385/10/12

#### Ethics committee reference number

85-2592

## Health conditions studied

### 1

#### Description of health condition studied

Preterm labor

#### ICD-10 code

060.0

#### ICD-10 code description

Preterm delivery without delivery

## Primary outcomes

### 1

#### Description

Contraction

#### Timepoint

Every 4 hours to first 24 hours and then every 12 hours for 2 times

#### Method of measurement

Medical examination

## Secondary outcomes

### 1

#### Description

blood pressure

#### Timepoint

every 15 minutes up to 2 hour and every hour up to 24 hours

#### Method of measurement

Manometer

### 2

#### Description

Shortness of breath

#### Timepoint

every 15 minutes up to 2 hour and every hour up to 24 hours

#### Method of measurement

asking the patient

### 3

#### Description

Tachycardia

#### Timepoint

every 15 minutes up to 2 hour and every hour up to 24 hours

#### Method of measurement

Measuring the pulse

## Intervention groups

### 1

#### Description

Intervention group: 10 mg oral Nifedipin is administered and if contractions continue for 15 minutes, the second

dose is administered and continued every quarter of an hour for 1 hour. Then a 10 mg Nifedipin capsule per 6 hours is administered and continued to 24 hours.

**Category**

Treatment - Drugs

**2****Description**

Control group: 4 grams magnesium sulfate in 200 cc Ringer serum is infused during 20 minutes and then 2 grams magnesium sulfate is infused per hour and continued up to 24 hours or 2 hours after contraction.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ali Ebne Abitaleb Hospital

**Full name of responsible person**

Dr. Maryam Khooshide

**Street address**

Salamat Street

**City**

Zahedan

**2****Recruitment center****Name of recruitment center**

Arash women's hospital

**Full name of responsible person**

Maryam Khoshideh

**Street address**

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Zahedan University of Medical Science

**Full name of responsible person**

Dr. Mohammad Hashemi

**Street address**

Khlije Fars boulevard

**City**

Zahedan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Zahedan University of Medical Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Science

**Full name of responsible person**

Dr. Maryam Khooshide

**Position**

gynecologist

**Other areas of specialty/work****Street address**

Arash Women Hospital, Rashid Street, Resalat Highway, Tehranpars

**City**

Tehran

**Postal code****Phone**

+98 21 7771 9922

**Fax****Email**

khooshide@tums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Science

**Full name of responsible person**

Dr. Maryam Khooshide

**Position**

gynecologist

**Other areas of specialty/work****Street address**

Arash Women Hospital, Rashid Avenue, Resalat Highway, Tehranparse

**City**

Tehran

**Postal code****Phone**

+98 21 7771 9922

**Fax****Email**

khooshide@tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Khooshide

**Position**

gynecologist

**Other areas of specialty/work****Street address**

Arash Womens Hospital, Rashid Avenue, Resalat  
Highway, Tehranparse

**City**

Tehran

**Postal code****Phone**

+98 217779922

**Fax****Email**

khooshide@tums.ac.ir

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*