

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comprasion of nifedipin versus magnesium sulfate in Treatment of preterm labor

#### Protocol summary

##### Summary

Preterm delivery is defined a birth occurring before 37 weeks of gestation or before 259 days from the last menstrual period and its incidence has increased during the last decade in most countries. Several drugs have been suggested for treatment of preterm labor but suitable and safe drug is not still available. The aim of this study is comparison of Nifedipin versus Magnesium Sulfate in treatment of preterm labor. 120 pregnant women in 24-34 gestational weeks who are admitted in Rohani Hospital of Babol because of preterm labor are randomly assigned to receive Magnesium Sulfate (n=60) or Nifedipine (n=60). Before enrolling in this study the informed consent from women is obtained. The first step of management is bed rest and hydration by 500cc infusion of ringer solution and 50 mg Pethedine IM for two groups. If contractions are continued all patients will receive Betamethasone 12mg IM twice, 24 hours apart and randomly receive either oral Nifedipine or intravenous Magnesium Sulfate. Demographic and obstetrics characteristics, maternal and fetus adverse effects, clinical assessment, time to failure of the treatment are record by questionnaire. Fetal distress and induced delivery are excluded from study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201301281760N20**  
Registration date: **2013-05-11, 1392/02/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-05-11, 1392/02/21

#### Registrant information

##### Name

Nargess Gholizadeh Pasha

##### Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3236 2282

##### Email address

zahra@mubabol.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

#### Expected recruitment start date

2012-12-10, 1391/09/20

#### Expected recruitment end date

2013-12-22, 1392/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comprasion of nifedipin versus magnesium sulfate in Treatment of preterm labor

#### Public title

Comprasion of nifedipin versus magnesium sulfate in Treatment of preterm labor

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: 24w-34w gestational age with a

diagnosis of preterm labor; at least four contractions[During the "30 in 20 minutes with increasing cervical dilatation and effacement] (2cm dilatation or effacement of 80%). Exclusion criteria: multiple pregnancies; corioamnionitis; preeclampsia, abruption previa, liver disease, heart and blood pressure, maternal vaginal bleeding; IUGR; IUFD; Fetal distress, fetal major anomaly; PPRM; (PR> 100, BP <90/50) <sup>3</sup> 5cm dilatation.

#### Age

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

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The ethics committee of Babol University of Medical Sciences

##### Street address

Babol University of Medical Sciences, Ganjafroz Avenue

##### City

Babol

##### Postal code

#### Approval date

2012-12-09, 1391/09/19

#### Ethics committee reference number

1671

## Health conditions studied

### 1

#### Description of health condition studied

preterm labor

#### ICD-10 code

O60

#### ICD-10 code description

Preterm labour and delivery

## Primary outcomes

### 1

#### Description

Premature birth control

#### Timepoint

Before 37 weeks of gestation

#### Method of measurement

Clinical

## Secondary outcomes

### 1

#### Description

Adverse effects of maternal magnesium sulfate versus nifedipine

#### Timepoint

Three days a week during the first 48 hours of onset of pain

#### Method of measurement

clinical

### 2

#### Description

Magnesium sulfate versus nifedipine complication rate of fetal tachycardia

#### Timepoint

Three days a week during the first 48 hours of onset of pain

#### Method of measurement

clinical

### 3

#### Description

The effect of nifedipine versus magnesium sulfate to stop the contractions of

#### Timepoint

Three days a week during the first 48 hours of onset of pain

#### Method of measurement

Clinical

## Intervention groups

### 1

#### Description

Intervention : Patients in Nifedipine group will receive 10mg orally and follow every 20 minutes for total four doses and assess for blood pressure. Then received 20 mg orally every 6 hours until 24 hours and every 8 hours until next 24 hours.

#### Category

Treatment - Drugs

## 2

### Description

Control: Patients in Magnesium Sulfate group will receive 4gr bolus and follow by 2gr/h infusion. All patient assess for urinary output, DTR, respiratory rate, The drug will continue until 12 hours after stopping of contractions.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rouhani hospital

##### Full name of responsible person

Mahboubeh Ramzani

##### Street address

##### City

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

##### Full name of responsible person

Dr. Ali Bijani

##### Street address

Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Gangafroz Avenue

##### City

Babol

##### 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 and Technology, Babol University of Medical Sciences

##### 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

Fatemehzahra Fertility & reproductive Health Reseach Center

#### Full name of responsible person

Nargess Gholizadeh Pasha

#### Position

MA/Responsible for Public Affairs of Research Center

#### Other areas of specialty/work

#### Street address

Fatemehzahra Fertility & reproductive Health Reseach Center, Noshirvani street

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#### Postal code

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+98 11 1227 4881

#### Fax

#### Email

ngh\_pa@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Fatemeh Zahra Fertility & Reproductive Health Research Center

#### Full name of responsible person

Dr. Nesa Asnafi

#### Position

Gynecologist

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Fatemeh Zahra Fertility & Reproductive Health Research Center

#### Full name of responsible person

Nargess Gholizadeh Pasha

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#### Other areas of specialty/work

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**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*