

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Magnesium Sulfate In Adverse With Nifedipine In Suppression Preterm labor In Pregnant With Preterm Labor

#### Protocol summary

##### Summary

In this study we want to suppress preterm labor and prevent mortality and morbidity of fetus and neonate .Mothers will check with include and exclude criteria: more than 6 contractions per hour resulting in a demonstrated cervical change or presumed prior cervical change (transvaginal cervical length < 2.5 cm, >50% cervical effacement, or cervical dilation  $\geq$  2 cm) ;Gestational ages are between 26-34 ; Bloody show ; Nully fetus pregnant ; Intact membranes ; BP>90 mmhg in Nifedipine group. Exclude criteria: Oligohydramnios and polyhydramnios ;Nonreactive nonstress test results ;Positive contraction stress test results ; Absent or reversed diastolic flow upon Doppler examination of umbilical blood flow ; Repetitive severe variable decelerations ;Significant vaginal bleeding consistent with abruption and placenta previa ; PPRM ;Multi fetus pregnancy ;BP<90 mmhg in Nifedipine group ; Intrauterine infection ; Pyelonefritis ;Preeclamps and GTM and anomalies. Our community will include pregnant women(26-34w) with preterm singes refers to Talegane and Azahra hospital .Sample size will be 80.Half of them will get Nifedipine and 40 mothers will get Magnesium Sulfate.These women are blocked into two groups by randomization.Efficiency and side effect of two drugs are compared .This study will continue approximately one year.The women of A group will be given Magnesium sulfate and group B will be given Nifedipine . These data will be evaluated by check list and partugram.Primary outcome will be Effacement and Dilatation that will be evaluated by vaginal examination. Length and duration of contractions will be evaluated by Abdominal tough of uterus Every 10 minute.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201308878N1**

Registration date: **2012-05-05, 1391/02/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-05-05, 1391/02/16

##### Registrant information

###### Name

Fereshteh Fartash

###### Name of organization / entity

Nursing and midwifery of tabriz medical university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1666 1428

###### Email address

fereshtefartash@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University Of Medical Science

##### Expected recruitment start date

2012-04-20, 1391/02/01

##### Expected recruitment end date

2013-04-21, 1392/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Magnesium Sulfate In Adverse With Nifedipine In Suppression Preterm labor In Pregnant With Preterm Labor

**Public title**

Magnesium Sulfate In Adverse With Nifedipine In suppression preterm labor In Pregnant With Preterm Labor

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Criteria include more than 6 contractions per hour resulting in a demonstrated cervical change or presumed prior cervical change (transvaginal cervical length < 2.5 cm, >50% cervical effacement, or cervical dilation  $\geq$  2 cm) ;Gestational ages are between 26-34 ; Bloody show ; Nully fetus pregnant ; Intact membranes ; BP>90 mmhg in Nifedipine group exclude criteria Oligohydramnios and polyhydramnios ;Nonreactive nonstress test results ;Positive contraction stress test results ; Absent or reversed diastolic flow upon Doppler examination of umbilical blood flow ; Repetitive severe variable decelerations ;Significant vaginal bleeding consistent with abruption and placenta previa ; PPRM ;Multi fetus pregnancy ;BP<90 mmhg in Nifedipine group ; Intrauterine infection ; Pyelonefrites ;Preeclamps and GTM and anomalies

**Age**

From **14 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Medical Science Of Tabriz University

**Street address**

Tabriz, Golgasht St.

**City**

Tabriz

**Postal code**

5138856913

**Approval date**

2011-11-21, 1390/08/30

**Ethics committee reference number**

9053

**Health conditions studied****1****Description of health condition studied**

Preterm labor

**ICD-10 code**

O60.0

**ICD-10 code description**

Preterm labour without delivery

**Primary outcomes****1****Description**

Effeement

**Timepoint**

In addmission

**Method of measurement**

Vaginal examination

**2****Description**

Dillatation

**Timepoint**

In admmission

**Method of measurement**

Vaginal examination

**3****Description**

Length and diuration of contractions

**Timepoint**

Every 10 minute

**Method of measurement**

Abdominal tough of uterus

**Secondary outcomes****1****Description**

Feeling of fetal movment by mother

**Timepoint**

In an hour

**Method of measurement**

Abdominal touching

**2****Description**

Unreliable paterns of fetal heart rate

**Timepoint**

In 20 minnutes

### Method of measurement

Record by monitoring devices

### 3

#### Description

Newborn Apgar

#### Timepoint

In first and fifth min.

#### Method of measurement

Apgars score

### 4

#### Description

ABG of umbilical cord blood

#### Timepoint

After birth

#### Method of measurement

ABG devices

### 5

#### Description

Meconium

#### Timepoint

After birth

#### Method of measurement

Finding meconium on newborn skin or amniotic fluid or umbilical cord

## Intervention groups

### 1

#### Description

First group (A) will be giving 4 gram Magnesium Sulfate as a loading dose then continuing 2 gram every hour until 48 hours(positive Patella reflex ,at least 12 times respiratory rates,urine output at least 30mm)at the same time this group will be giving Placebo tablet instead of Nifedipine

#### Category

Treatment - Drugs

### 2

#### Description

The other group will be giving Nifedipine tablet(20mg) after half an hour will be given other 20 mg of Nifedipine tablet,if contractions persist ,giving 20 mg Nifedipin will be continuing every 3-8 hours until contractions will subside.at the same time serum Ringer with microset will be conduct as Plasebo

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

#### Name of recruitment center

Azahra hospital

#### Full name of responsible person

Fereshteh Fartash

#### Street address

Bageshomal square

#### City

Tabriz

### 2

#### Recruitment center

#### Name of recruitment center

Talegane hospital

#### Full name of responsible person

Fereshteh Fartash

#### Street address

Railway square

#### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Tabriz University Of Medical Sciences

#### Full name of responsible person

Fahimeh Sehhatie shafae

#### Street address

Nurcing And Midwifery University, Sought Shariaty Street

#### City

Tabriz

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz 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

Nursing and Midwifery University of Tabriz

#### Full name of responsible person

Fereshteh Fartash

#### Position

Master Degree Of Midwifery Student

**Other areas of specialty/work**

**Street address**

Sought Shariaty Street

**City**

Tabriz

**Postal code**

5138851559

**Phone**

+98 41 1666 1428

**Fax**

+98 41 1666 1428

**Email**

fereshtefartash@gmail.comfereshtehfartash@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Nursing And Midwifery Of Tabriz University

**Full name of responsible person**

Fahimeh Sehhatieh Shafae

**Position**

Master Degree

**Other areas of specialty/work**

**Street address**

Sought Shariaty Street

**City**

Tabriz

**Postal code**

5138856913

**Phone**

+98 41 1477 7379

**Fax**

+98 66 61428

**Email**

Fahimehsehhatie@yahoo.comsehhatief@tbzmed.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Nursing And Midwifery Of Tabriz University

**Full name of responsible person**

Fereshteh Fartash

**Position**

Student Of Master Degree Of Midwifery

**Other areas of specialty/work**

**Street address**

Sought Shariaty Street

**City**

Tabriz

**Postal code**

5138856913

**Phone**

+98 41 1666 1428

**Fax**

+98 41 1666 1428

**Email**

fereshtefartash@gmail.comfereshtehfartash@yahoo.com

**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*