

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effectiveness of Nifedipine and magnesium sulfate in treating preterm labor.

Protocol summary

Summary

Aim of this study was comparing the effectiveness of nifedipine and magnesium -sulfate in treating preterm labor. during the year 2011, a group of 110 cases of preterm labor at their 27th-36th of Gestation were entered and blindly divided into two groups of 55 patients. While, one group was treated with oral Nifedipine, the other was administered intravenous Mg-sulfate. inclusion criteria were 4 contractions per 20 min, while dilatation of cervixes were > 1cm & effacement > 85 % and Exclusion criteria were rupture of membranes, vaginal bleeding, fetal distress, dilatation of cervix >3cm, and a blood pressure below 90/50 mm Hg. cases were treated either by 10 mg of nifedipine orally repeated up to 4 doses per 20/min which was continued by 20mg/4-8hr and then every 12 hours or by 4gr/20min of Mg-Sulfate intravenously which was continued by 1g/hr up to 24hr, in case of no contraindications treatments were continued till 48hr or 12hr after clinical responses for nifedipine and 24hr for mg-sulfate groups. 48 hours of treatments were watched and patients were controlled for contractions. if no contractions were observed it was considered as clinical response, meanwhile headache, hypotension, dyspnea and tachycardia considered as maternal complications and neonatal outcome was described by 1st min Apgar score.

General information

Acronym

preterm / threatened preterm labor and Nifedipine

IRCT registration information

IRCT registration number: **IRCT2013052113421N1**

Registration date: **2015-02-20, 1393/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-20, 1393/12/01

Registrant information

Name

Fariba Nanbakhsh

Name of organization / entity

Urmia University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

research deputy of urmia university of medical sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of Nifedipine and magnesium sulfate in treating preterm labor.

Public title

Comparing the effectiveness of Nifedipine and magnesium sulfate in treating preterm labor.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Patients in 27th-36th of Gestation; 4

contractions per 20 min; dilatation of cervixes > 1cm; effacement > 85 % ; intact membranes; have gestational age determined by LMP or ultrasonographical study; Not to be included if : any indication for termination of pregnancy; any previous medication as tocolysis ; Placental abruption; infection; contra indications of ca-blocker usage; primarily, a blood pressure below 90/50; Exclusion : were rupture of membranes; vaginal bleeding; fetal distress; dilatation of cervix >3cm; blood pressure below 90/50 mm Hg.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

N/A

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

Reproductive health research center

Street address

urmia, kashani street, Reproductive health research center, health center No6, third flour, No 42

City

urmia

Postal code

57156-65895

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

56

Health conditions studied

1

Description of health condition studied

Preterm labour

ICD-10 code

O60.0

ICD-10 code description

Preterm labour without delivery

Primary outcomes

1

Description

hampering contractions of labor.

Timepoint

48 hours from beginning of treatments.

Method of measurement

observation by gynecologist.

Secondary outcomes

1

Description

maternal complications : headache, hypotension, dyspnea and tachycardia.

Timepoint

48 hours of medication.

Method of measurement

observation and physical examination by gynecologist

2

Description

Neonatal outcome : 1st min Apgar score.

Timepoint

Just exact after labor.

Method of measurement

Physical examination & observation by gynecologist.

Intervention groups

1

Description

In Nifedipine group : Patients were treated by 10 mg of nifedipine orally repeated up to 4 dozes per 20/min which was continued by 20mg/4-8hr and then every 12 hours till 48hr or 12hr after clinical responses.

Category

Treatment - Drugs

2

Description

In Mg-sulfate group : Patients were treated by 4gr/20min of Mg-Sulfate intravenously which continued by 1g/hr up to 24hr, in case of no contraindications treatment continued till 24hr or for 24hr after clinical responses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital of Urumia, gynecology department

Full name of responsible person

Dr. Fariba nanbakhsh

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

urmia university of medical sciences, deputy of research and technology.

Full name of responsible person

Dr. Firouz Ghaderi Pakdel,

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Urumia University of Medical science, Resalat Ave, Urgans Street.

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Urumia

Grant name

00

Grant code / Reference number

00

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

Yes

Title of funding source

urmia university of medical sciences, deputy of research and technology.

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**

Urumia University of Medical Science

Full name of responsible person

Dr. Fariba nanbakhsh

Position

Associate Professor / Gynecologist, Fellowship of Infertility.

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

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Person responsible for scientific inquiries

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Position

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Full name of responsible person

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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