Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 cervices 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 dozes 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 nifedepine 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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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 cervices > 1cm; effacement > 85 % ; intact membranes; have gestational age determined by LMP or ultrasonogeraphical study; Not to be included if : any indication for termination of pregnancy; any previous medication as tocolysis ; Placental abruption; infection; contra indictions 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, genycology department

Full name of responsible person
Dr. Fariba nanbakhsh

Street address
Kosar Hospital of Urumia, Kashani Street,

City
Urmia

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,

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

City
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
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Position
Associate Professor / Gynecologist, Fellowship of Infertility.

Other areas of specialty/work

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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