Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comprasion of nifedipin versus magnesium salfate 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
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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 salfate in Treatment of preterm labor

Public title

Comprasion of nifedipin versus magnesium salfate 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; PPROM; (PR> 100, BP <90/50) ³ 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
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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
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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