Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of magnesium sulfate and nifedipine in the successful treatment of preterm labor

Protocol summary

Summary

This is a randomized clinical trial. The aim of this study was to compare the effect of nifedipine and magnesium sulfate for treatment of preterm labor. Participants were 100 singleton pregnant women between 24 to 37 weeks of gestation with signs of preterm labor referred to Alzahra hospital in 2003. Exclusion criteria was maternal or fetal indications of pregnancy termination. After obtaining Consent letter, Women were divided in two groups: nifedipine and magnesium sulfate. Vital signs, vaginal bleeding, rupture of membranes, fetal heart rate, and uterine contractions were monitored.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012062310089N1**
Registration date: **2013-06-07, 1392/03/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-07, 1392/03/17

Registrant information

Name
Roya Faraji Darkhaneh
Name of organization / entity
Guilan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Guilan University of Medical Sciences

Expected recruitment start date

2003-03-03, 1381/12/12

Expected recruitment end date

2004-06-16, 1383/03/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of magnesium sulfate and nifedipine in the successful treatment of preterm labor

Public title

Magnesium sulfate and nifedipine on treatment of preterm labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Singleton pregnancy, 24 to 37 weeks of gestation, signs of preterm labor. Exclusion criteria : premature rupture of membrane, cervical dilatation > 4 cm, gestational age < 24 or >37 weeks, chorioamnionitis, vaginal bleeding, multiple pregnancy, previous cesarean section, previous uterus surgery, maternal or fetal indications for termination of pregnancy such as preeclampsia, fetal distress, fetal growth abnormalities and decreased blood pressure.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This study is random

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee Vice Chancellor for Research of Guilan University of Medical Sciences
Street address
Vice Chancellor for Research, Guilan University of Medical Sciences, Namjo Street
City
Rasht
Postal code
Approval date
2003-03-03, 1381/12/12
Ethics committee reference number
336

Health conditions studied

1

Description of health condition studied
Preterm labor and delivery
ICD-10 code
O60.2
ICD-10 code description
Preterm spontaneous labor with term delivery

Primary outcomes

1

Description
Delaying delivery up to 48 hours
Timepoint
Every 15 minutes until stopping of uterine contractions
Method of measurement
Abdominal palpation of uterus

Secondary outcomes

1

Description
Cervical dilatation
Timepoint
Every 2 hours until stopping of uterine contractions
Method of measurement
Vaginal examination

2

Description
Uterine contractions
Timepoint
Every 15 minutes until stopping of uterine contractions
Method of measurement
Abdominal palpation of uterus

3

Description
Cervical effacement
Timepoint
Every 2 hours until stopping of uterine contractions
Method of measurement
Vaginal examination

4

Description
Fetal complications
Timepoint
During drug administration
Method of measurement
Physician assessment

5

Description
Maternal complications
Timepoint
During drug administration
Method of measurement
Physician assessment

Intervention groups

1

Description
Intravenous loading dose infusion was 4gr magnesium sulfate (20%) during 30 minutes, followed by a maintenance dose of 2 gr/hr until stopping or reducing uterine contractions. (magnesium sulfate heptahydrate 20% produced by Samen pharmaceutical company, Iran.)
Category
Treatment - Drugs

2

Description

We have used one capsule nifedipine (10 mg sublingual from Dana pharmaceutical company, Iran and its Generic name was Nifi-Gel). If uterine contractions persisted, we would use another capsule every 15 minutes; until a maximum dose of 40mg for one hour. Depending on tocolytic effects of nifedipine that we have used during one hour, we used a minimal dose of 60 mg every day. After 3 days, the dose would be decreased gradually and patient will receive 20 mg/day nifedipine up to 36 weeks of gestation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital, Guilan University of Medical sciences

Full name of responsible person
Dr.Roya Faraji Darkhaneh

Street address
Namjo street, Alzahra Hospital

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Guilan University of Medical Sciences

Full name of responsible person
Dr. Abdolrasol Sobhani

Street address
Vice Chancellor for Research, Guilan University of Medical Sciences, Namjo street

City
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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, Guilan 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
Guilan University of Medical Sciences

Full name of responsible person
Dr.Roya Faraji Darkhaneh

Position
Associated Professor Guilan University of Medical Sciences

Other areas of specialty/work

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Namjo street, Alzahra Hospital, Reproductive Health Research Center

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Person responsible for scientific inquiries

Contact

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Position
Associated Professor of Obstetrics group, Guilan University of Medical Sciences

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
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Other areas of specialty/work

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00
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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