Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial comparing the effect of 300 milligram intramuscular progesterone with oral nifedipine on threatened preterm labor in pregnant women hospitalized with threatened preterm labor

Protocol summary

Summary

We intended to compare the tocolytic effect of 300 milligram intramuscular progesterone with oral nifedipine on threatened preterm labor in pregnant women hospitalized in Akbarabadi Hospital with threatened preterm labor from 2011-1012. 497 cases entered the study. All women with single fetus pregnancy, aged 18-45, who referred with active uterine contractions and admitted for threatened preterm labor were enrolled to our study. Any patient with active phase of labor, or active infection, or any fetal problem will be excluded. The patients were then randomized according to a simple randomization (toss of a coin) and were divided into two groups: one group will receive 200 milligram intramuscular progestrone and the other group will receive oral nifedipine as tocolytic agents and will be followed until stopping uterine contractions. The researchers measuring the outcomes and the analyzer were blind about the type of intervention each patient was receiving. Then the tocolytic effect of drugs on treatment of threatened preterm labor will be compared. Outcomes, such as age at delivery, type of delivery, fetal birth weight will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112198469N1**
Registration date: **2015-12-08, 1394/09/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-08, 1394/09/17

Registrant information

Name

Zahra Najmi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2011-12-20, 1390/09/29

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effect of 300 milligram intramuscular progesterone with oral nifedipine on threatened preterm labor in pregnant women hospitalized with threatened preterm labor

Public title

Is intramuscular progesterone as effective as oral nifedipine for treating threatened preterm labor?

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women aged 18-45 years; women with single pregnancy; women with pregnancy between 26-34 weeks of gestational age; women who referred with active uterine contractions and admitted for threatened preterm labor. Exclusion criteria: women with active labor phase (Cervical dilatation>3cm; vaginal bleeding; rapture of membrane; over distension of the uterus (multifetal gestation or polihydramnios); any systemic infection; oral temperature>38; intrauterine growth retard (IUGR) fetus; fetal distress; blood pressure>140/90 mmHg; any contraindication for progestrone or nifedipine administration; history of any thromboembolic disorders.

Age
From **18 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
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committe of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd., Tehran, Iran

City
Tehran

Postal code

Approval date
2011-06-15, 1390/03/25

Ethics committee reference number
338

Health conditions studied

1

Description of health condition studied
Preterm Labor

ICD-10 code
o60

ICD-10 code description
Preterm labour without delivery

Primary outcomes

1

Description
Stopping uterine contractions

Timepoint
Before intervention, each hour until contractions stop, 12 hours after stopping contractions

Method of measurement
Tocometry

Secondary outcomes

1

Description
Delivery time

Timepoint
Date of neonate's birth

Method of measurement
Gestational age at the time of delivery

2

Description
Reccurance of preterm contractions

Timepoint
every week

Method of measurement
tocometry

3

Description
Neonate status

Timepoint
Time of delivery, time of discharge

Method of measurement
Apgar score, hospitalization period, need for NICU

Intervention groups

1

Description
Intervention 1: Intra-mascular progestrone 200 mg (100 mg in each gluteus maximus)

Category
Treatment - Drugs

2

Description
Intervention 2: Oral nifedipine with standard dosage (started with a loading dose of 30 mg and continued with 10-20 mg every 4-6 hours until pain relief)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar-Abadi hospital
Full name of responsible person
Zahra Najmi
Street address
Shahid Akbar-Abadi Hospital, Molavi Square, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Ali Javad Musavi
Street address
Research Deputy office of Iran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

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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