

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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 progesterone 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

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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; rupture of membrane; over distension of the uterus (multifetal gestation or polyhydramnios); any systemic infection; oral temperature>38; intrauterine growth retard (IUGR) fetus; fetal distress; blood pressure>140/90 mmHg; any contraindication for progesterone 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 Committee 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 progesterone 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

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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

Contact

Name of organization / entity

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Zahra Najmi

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Person responsible for scientific inquiries

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty