Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison effect of oral Dydrogesterone on the treatment of preterm labor with oral Nifedipine in pregnant women admitted with a diagnosis of risk of preterm labor

Protocol summary

Study aim

Determining and comparing the effect of oral dydrogesterone on the treatment of preterm delivery with oral nifedipine in pregnant women admitted with diagnosis at risk of preterm delivery

Design

A clinical trial study of 60 women aged 18-45 years with a singleton pregnancy of 26-34 weeks hospitalized with a diagnosis of preterm delivery who were admitted to the study at the first visit and with a diagnosis of preterm delivery by double-blind random sampling.

Settings and conduct

For research, we need basic information such as age, gestational age, BMI, Threatened Preterm Labor, Preterm Labor, Preterm Delivery, PTL history, nifedipine use and Dydrogestrerone use. It is performed in Shahid Akbar Abadi and Hazrat Rasoul hospitals.

Participants/Inclusion and exclusion criteria

A total of 60 women aged 18-45 years with a singleton pregnancy of 26-34 weeks, admitted with a diagnosis of preterm labor, are included in the study. Exclusion criteria include any maternal or fetal conditions that require immediate delivery (including fetal distress; placenta abruption; chorioamnionitis; severe preeclampsia; Patients who have entered the active phase of labor (cervical dilatation>=4cm); vaginal bleeding; Ruptured of membrane; Uterine distention for example due to multiple pregnancy and polyhydramnios; The presence of any systemic infection; Fever greater than 38 degrees Centigrade; Intrauterine growth restriction; Blood pressure above 140/90 mm Hg; Fetal anomalies; Contraindications to the use of tocolytics, allergy to progesterone and a history of any thromboembolic disease.

Intervention groups

This interventional study is a randomized clinical trial that is performed on 60 single pregnant women with a gestational age of 26-34 weeks .

Main outcome variables

Study variables include dydrogesterone, preterm delivery, gestational age, neonatal complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180227038892N1**
Registration date: **2020-11-10, 1399/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-10, 1399/08/20**
Update count: **0**

Registration date

2020-11-10, 1399/08/20

Registrant information

Name

Neda Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8825 9024

Email address

nedahashemi1363@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of oral Dydrogesterone on the treatment of preterm labor with oral Nifedipine in pregnant women admitted with a diagnosis of risk of preterm labor

Public title

effect of oral Dydrogesterone on the treatment of preterm labor

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

A total of 60 women aged 18-45 years with a singleton pregnancy of 26-34 weeks, admitted with a diagnosis of preterm labor, are included in the study.

Exclusion criteria:

Exclusion criteria include any maternal or fetal conditions that require immediate delivery (including fetal distress; placenta abruption; chorioamnionitis; severe preeclampsia; Patients who have entered the active phase of labor (cervical dilatation>=4cm); vaginal bleeding; Ruptured of membrane; Uterine distention for example due to multiple pregnancy and polyhydramnios; The presence of any systemic infection; Fever greater than 38 degrees Centigrade; Intrauterine growth restriction; Blood pressure above 140/90 mm Hg; Fetal anomalies; Contraindications to the use of tocolytics, history of any allergy to progesterone and a history of any thromboembolic disease.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomly receive the first dose of 40 mg oral dydrogesterone and the second group oral standard nifedipine at the standard dose for tocolytic, and the results obtained from mothers and infants are compared in the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients after hospitalization in the maternity ward are randomly divided into one of the following two groups. The first group received 40 mg of oral dydrogesterone and after 8 hours, uterine contractions were monitored again by a tocometer. if Uterine contractions do not stop , continue a dose of 10 mg every 8 hours for 48 hours. If uterine contractions do not decrease after 8 hours with this drug, patients will be treated with nifedipine. And the second group will receive oral nifedipine at a standard dose according to the protocol (starting with a dose of 10 mg every 20 minutes to an hour and continuing with 20 mg every 6 hours to 24 hours and then 20 mg every 8 hours to the next 24 hours)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of medicine- Iran university of medical science

Street address

Hemmat Highway-IRAN university of medical science

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-01-08, 1395/10/19

Ethics committee reference number

IR.IUMS.REC.1395.9211290013

Health conditions studied

1

Description of health condition studied

Preterm labor

ICD-10 code

O60

ICD-10 code description

Preterm labor

Primary outcomes

1

Description

preterm labor

Timepoint

It is checked at the beginning of the study and then 8 hours later.

Method of measurement
vaginal examination and cervical asessment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receive 40 mg of oral dydrogesterone and after 8 hours, uterine contractions are monitored again by a tocometer. If uterine contractions are reduced, the same drug is continued at a dose of 10 mg every 8 hours for 48 hours. If uterine contractions do not decrease after 8 hours with this drug, patients will be treated with nifedipine.
Category
Prevention

2

Description
Control group: Oral nifedipine is administered at a standard dose according to the protocol (starting with 10 mg every 20 minutes to one hour and continuing with 20 mg every 6 hours to 24 hours and then 20 mg every 8 hours for the next 24 hours).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Neda hashemi
Street address
Sattar Khan St., Niayesh St., Hazrat Rasool Akram Hospital
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2434
Email
nedahashemi1363@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Samedihe khoee
Street address
Iran university o medical scirnce-Research Assistant-Hemmat high way
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
PR@iums.ac.ir
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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Neda hashemi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Sattar Khan St., Niayesh St., Rasoul Akram Hospital
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6650 9283
Email
nedahashemi1363@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Neda hashemi

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Sattar Khan St., Niayesh St., Rasoul Akram Hospital

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6650 9283

Email
nedahashemi1363@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Neda hashemi

Position
assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Sattar Khan St., Niayesh St., Rasoul Akram Hospital

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6650 9283

Email
nedahashemi1363@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Drugs dosage, sampling method and study results are shared.

When the data will become available and for how long
Is given at the end of the research.

To whom data/document is available
People working in university centers.

Under which criteria data/document could be used
For scientific promotion of university centers

From where data/document is obtainable
See the email below. nedahashemi1363@yahoo.com

What processes are involved for a request to access data/document
First, the investigation should be completed and the applicant should send an e-mail stating all the details of his specifications, and his application will be reviewed, and if the information is approved, it will be sent to him. The time will be determined after the end of the research

Comments