

# 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 Dydrogesterone 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  $\geq 4$ cm); 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  $\geq 4$ cm); 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 assessment

## 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

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##### Postal code

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##### 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

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## 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**

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1445613131

**Phone**

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**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**