Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Checking the effect of oral Dydrogesterone (Duphaston) on preventing preterm labor: A Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of oral Dydrogesterone on preventing preterm labor for the mothers who have experienced the treated preterm labor.
Design
Clinical trial includes an intervention, a controlled and a randomized group with parallel groups.
Settings and conduct
Sampling takes place in Amir-AlMoemenin hospital.
Participants/Inclusion and exclusion criteria
The criteria of entering the study includes gestational age from 24 to 34 weeks; exclusion criteria of entering the study is premature rupture of membranes (PROM). The population of the study are pregnant women with preterm labor pain diagnosis.
Intervention groups
Intervention group will be treated with Dydrogesterone capsule (10 milligrams, twice a day). The control group will receive placebo.
Main outcome variables
checking uterine contractions and gestational age during labor

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190107042266N1**
Registration date: **2019-03-04, 1397/12/13**
Registration timing: **prospective**

Last update: **2019-03-04, 1397/12/13**
Update count: **0**
Registration date
2019-03-04, 1397/12/13

Registrant information

Name
Samaneh Lavvaf
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-03-20, 1397/12/29
Expected recruitment end date
2019-09-22, 1398/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Checking the effect of oral Dydrogesterone (Duphaston) on preventing preterm labor: A Randomized Clinical Trial

Public title
Checking the effect of oral Dydrogesterone (Duphaston) on preventing preterm labor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
From the age of 18 to 45 Gestational age of 24 to 34 weeks (calculation based on first trimester sonography) Not having PLP 48 hours after treatment Single pregnancy Not of smoking
Exclusion criteria:
Placenta Previa Premature rupture of membranes

Chorioamnionitis Severe preeclampsia The use of progesterone before the study Contraindication of progesterone Contraindication of Tocolytic Dilatation more than 4 centimeters Fetal anomalies Dissatisfaction of the patient to continue participating in the study Pregnancy scar Cervical cerclage

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Using randomized blocks due to the kind of treatment for pregnant women with the criterion of entering the study is divided into two groups: controlled and intervention groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be unaware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2017-10-03, 1396/07/11

Ethics committee reference number

IR.SEMUMS.REC.1397.199

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 before the 37th week of pregnancy

Timepoint

From the beginning of the intervention (from the beginning of preterm labor up to the gestational age of 24 to 34 weeks) until the occurrence of the preterm labor (gestational age of 36 weeks and 6 days)

Method of measurement

Visiting the patient every other two weeks for the relapse of preterm labor pain, regular use of drugs, drug based side effects like nausea, dizziness and exhaustion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dydrogesterone capsule with the dose of 10 milligrams, 2 tablets per day is prescribed after lunch and dinner and until the gestational age of 36 weeks and 6 days or it continues until the occurrence of the labor.

Category

Treatment - Drugs

2

Description

Control group: placebo with a very similar shape and size with Dydrogesterone capsule is prescribed twice a day after lunch and dinner and continues until the gestational age of 36 weeks and 6 days or until the occurrence of the labor.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-AlMoemenin hospital

Full name of responsible person
Dr Mojgan Rahmanian
Street address
Amir-AlMomenin hospital, Mostafa Khomeini Blvd
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Sponsors / Funding sources

1

Sponsor
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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
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Dr Mojgan Rahmanian
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available