Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Effectiveness of progesterone, Duphaston, and placebo to increase gastaional age in preterm labor

Protocol summary

Study aim
Comparison the effectiveness of Progesterone and Duphaston as tocolytic agents vs placebo, to prevent from preterm labor and its complication.

Design
Randomized clinical trial with 2 intervention group and 1 control group / parallel groups.

Settings and conduct
Sampling will be conducted in Imam Reza, Ghaem and Om-mol-banin hospitals of Mashhad.

Participants/Inclusion and exclusion criteria
Gestational age between 24-34 weeks / Maternal age between 18-37 years old / Singleton pregnancy / Contractions occur one to eight minutes apart / Dilatation less than 3 cm. / Effacement less than 80 percent / intact amniotic membrane.

Intervention groups
The first intervention group receives Duphaston tab (10 mg/ twice per day), the second one receives Progesterone suppository (200 mg daily) and third group or control / placebo, receives none of them.

Main outcome variables
Uterine contractions and gestational age at delivery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180303038922N1**
Registration date: **2018-03-17, 1396/12/26**
Registration timing: **prospective**

Last update: **2018-03-17, 1396/12/26**
Update count: **0**

Registration date
2018-03-17, 1396/12/26

Registrant information

Name
Zeynab Khademi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3840 0000

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khademiz2@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2019-04-20, 1398/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of progesterone, Duphaston, and placebo to increase gastaional age in preterm labor

Public title
Effectiveness of progesterone, Duphaston, and placebo to prevent preterm birth

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Gestational age between 24-34 weeks Maternal age between 18-37 years old Singleton pregnancy Contractions occur one to eight minutes apart. Dilatation less than 3 cm. Effacement less than 80 percent intact amniotic membrane

Exclusion criteria:
Maternal or fetal conditions that necessitate urgent delivery fetal anomalies Evidence for tocolytic drug contraindication Allergy to progestrone

Age
From **18 years** old to **37 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
Random number table

Blinding (investigator's opinion)
Not 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 Mashhad University of Medical Sciences

Street address
Qoreishi Building, Daneshgah Street.

City
Mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2017-10-11, 1396/07/19

Ethics committee reference number
IR.MUMS.FM.REC.1396.416

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
Uterine contractions

Timepoint
every 2 weeks until 36 weeks and then weekly.

Method of measurement
Uterine contractions are measured by Cardiotachometer.

Secondary outcomes

1

Description
Gestational age at labor

Timepoint
every 2 weeks until 36 weeks and then weekly

Method of measurement
gestational age in weeks (based on first trimester ultrasound)

Intervention groups

1

Description
Intervention group: Duphaston group

Category
Treatment - Drugs

2

Description
Intervention group: progesterone group

Category
Treatment - Drugs

3

Description
Control group: No intervention

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital

Full name of responsible person
Zeynab Khademi

Street address
Ahmad abad street.

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2

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Om-mol-banin hospital
Full name of responsible person
Zeynab Khademi
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Ayatollah Behjat Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Marzieh Lotfalizadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
To protect the privacy of the participants in the study.
Study Protocol
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable