

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of progesterone, Duphaston, and placebo to increase gestational 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)

Phone

+98 51 3840 0000

Email address

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 gestational 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 progesterone

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

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Ahmad abad street.

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2

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Zeynab Khademi
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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vcresearch@mums.ac.ir

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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Imam Reza hospital. Imam Reza square.
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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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Zeynab Khademi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics