Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of vaginal progesterone on uterine Doppler findings in early-onset preeclampsia

Protocol summary

Study aim
Comparison of the effect of vaginal progesterone on uterine Doppler findings in early-onset preeclampsia

Design
This study was designed as a single-blinded randomized clinical trial with parallel groups and a sample size of40 people in each group.

Settings and conduct
The study will be conducted at Kamali Hospital on pregnant women. Patients who signed informed consent will be randomly divided into two groups. The first group will receive progesterone suppository 200 mg daily for one week. The control group will not receive an intervention The final outcome of the study will be assessed by a third party who is unaware of the study process. Also, the statistician will be unaware of the study process

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age between 24-32 weeks; Increased uterine artery resistance; Single pregnancy; Patients with a history of lupus antiphospholipid syndrome; History of high blood pressure; Previous history of preeclampsia; Diabetic Exclusion criteria: Having kidney, liver, and heart disease;e Having progesterone sensitivity Having severe preeclampsia Rupture of membranes; Patients with cardiomyopathy; Evidence of fetal growth retardation; Ultrasound evidence of life-threatening congenital anomalies; Use assisted reproductive techniques such as IVF

Intervention groups
Intervention group: Progesterone suppository 200 mg daily for one week Control group: Without intervention

Main outcome variables
Uterine artery Doppler resistance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210127050156N1**
Registration date: **2021-03-03, 1399/12/13**
Registration timing: **prospective**

Last update: **2021-03-03, 1399/12/13**
Update count: **0**

Registration date
2021-03-03, 1399/12/13

Registrant information

Name
Masoumeh Farahani

Name of organization / entity
The Alborz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2236 5627

Email address
m.farahanii@abzums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-20, 1399/12/30

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of vaginal progesterone on uterine Doppler findings in early-onset preeclampsia

Public title
Comparison of the effect of vaginal progesterone on uterine Doppler findings in early-onset preeclampsia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
gestational age between 24-32 weeks Increased uterine artery resistance Single pregnancy Patients with a history of lupus antiphospholipid syndrome History of high blood pressure Previous history of preeclampsia Diabetic
Exclusion criteria:
Having kidney, liver and heart disease Having progesterone sensitivity Having severe preeclampsia Rupture of membrance Patients with cardiomyopathy; Evidence of fetal growth retardation; Ultrasound evidence of life-threatening congenital anomalies Use assisted reproductive techniques such as IVF
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
First, this study is done as a pilot, and then, based on the results, the sample size is determined. Simple randomization approach will be implemented in this study. Randomization will be performed using a computer-generated list. For this purpose, 80 sealed envelopes will be numbered 1-80 according to the randomization list. Group allocation will be kept separate until the study is completed. The randomization ratio would be 1: 1, with 40 envelopes allocated to each group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind. Due to the type of intervention, participants are aware of the type of treatment
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
City
Tehran
Province
Tehran
Postal code
3149779453
Approval date
2020-11-21, 1399/09/01
Ethics committee reference number
IR.ABZUMS.REC.1399.245

Health conditions studied

1

Description of health condition studied
Preeclampsia
ICD-10 code
O14
ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
Uterine artery resistance
Timepoint
Before and one week after the intervention
Method of measurement
Doppler ultrasound

2

Description
Symptoms of preeclampsia
Timepoint
During pregnancy
Method of measurement
Doctor's opinion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Progesterone vaginal suppository 200 mg (Aburaihan pharmaceutical company) every night for one week

Category

Treatment - Drugs

2

Description

Control group: Without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Masoomeh Farahani

Street address

Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street

City

Tehran

Province

Tehran

Postal code

3149779453

Phone

+98 26 3222 2021

Email

m.farahanii@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

Street address

Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

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karaj

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3198764653

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Masoomeh Farahani

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Masoomeh Farahani
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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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