Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the effect of vaginal progesterone administration on ultrasonographic indicators and fetal and pregnancy outcomes of women at high risk of preeclampsia

Protocol summary

Study aim

Evaluation of the effect of vaginal progesterone administration on ultrasonographic indicators and fetal and pregnancy outcomes of women at high risk of preeclampsia

Design

Clinical trial with parallel control group, double blind, randomized, single center trial, Sample size 40 people.

Settings and conduct

Amiralmomenin Hospital In this study, the vascular resistance index and uterine artery pulsatility index, which are related to the use of aspirin and progesterone, are examined immediately before and 6 weeks after the start of the intervention. The patient and the specialist doctor evaluating the patients and the radiologist will remain unaware of the type of patient grouping and the drug used by each group.

Participants/Inclusion and exclusion criteria

The statistical population includes pregnant women referring to the women's clinics of Amirul Mominin Semnan. Inclusion criteria: Age 18 and above; Body mass index above 30; The interval between pregnancies is more than 10 years; Multiple pregnancy; Pre-gestational diabetes, Live singleton fetus. Exclusion criteria: Heart, liver, thyroid diseases, history of asthma; Aspirin sensitivity; Threatened abortion such as vaginal bleeding; Eclampsia and pre-eclampsia at the time of study.

Intervention groups

Intervention group: In this group; Treatment with oral aspirin tablets (Cardiosprin 80 grams, manufactured by Samisaz, Iran) on a daily basis from the 12th week of pregnancy to the 36th week; Together with vaginal progesterone suppositories (Cyclogest 400 mg, manufactured by Octoverco, Iran) daily from the 12th week of pregnancy to the 34th week. Control group: In this group; Treatment with oral aspirin tablets (Cardiopirin 80 grams, manufactured by Samisaz Company, Iran) is performed daily from the 12th week of pregnancy to the 36th week.

Main outcome variables

Vascular Resistance Index (RI), Pulsatile index (PI).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N72**
Registration date: **2022-09-05, 1401/06/14**
Registration timing: **prospective**

Last update: **2022-09-05, 1401/06/14**
Update count: **0**

Registration date

2022-09-05, 1401/06/14

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-11, 1401/06/20

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vaginal progesterone administration on ultrasonographic indicators and fetal and pregnancy outcomes of women at high risk of preeclampsia

Public title

Evaluation of the effect of vaginal progesterone administration on ultrasonographic indicators and fetal and pregnancy outcomes of women at high risk of preeclampsia

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 and above Body mass index above 30 The interval between pregnancies is more than 10 years Multiple pregnancy Pre-gestational diabetes Live singleton fetus

Exclusion criteria:

Heart, liver, thyroid diseases, history of asthma Aspirin sensitivity Threatened abortion such as vaginal bleeding Eclampsia and pre-eclampsia at the time of study

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA, and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 15 units of 4 blocks will be selected so that we consider having 30 people in the group (A) and 30 people in the group (B). Therefore, we will do block randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug packaging is coded. So that the evaluators and patients are unaware of the drug content packaging and intervention that they receive.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2022-04-25, 1401/02/05

Ethics committee reference number

IR.SEMUMS.REC.1401.018

Health conditions studied

1

Description of health condition studied

High risk pregnancy

ICD-10 code

O09

ICD-10 code description

Supervision of high risk pregnancy

Primary outcomes

1

Description

Vascular Resistance Index (RI)

Timepoint

Before the intervention and 6 weeks after the intervention

Method of measurement

Color Doppler ultrasound

2

Description

Pulsatile index (PI)

Timepoint

Before the intervention and 6 weeks after the intervention

Method of measurement

Color Doppler ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group; Treatment with oral aspirin tablets (Cardiosprin 80 grams, manufactured by Samisaz, Iran) on a daily basis from the 12th week of pregnancy to the 36th week; Together with vaginal progesterone suppositories (Cyclogest 400 mg, manufactured by Octoverco, Iran) daily from the 12th week of pregnancy to the 34th week.
Category
Diagnosis

2

Description
Control group: In this group; Treatment with oral aspirin tablets (Cardiopirin 80 grams, manufactured by Samisaz Company, Iran) is performed daily from the 12th week of pregnancy to the 36th week.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al-Momenin Hospital
Full name of responsible person
Satinik Darzi
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Majid Mirmohammadkhani
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan.
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
majidmirmohammadkhani@yahoo.com
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
Satinik Darzi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Satinik Darzi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Satinik Darzi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

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
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available