

# 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

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##### Province

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##### Email

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## 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

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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**

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

**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