

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of progesterone and two different doses of aspirin effect on refusing uterine artery resistance and pregnancy outcome

Protocol summary

Study aim

Comparing the effect of progesterone and two different doses of aspirin in reducing uterine artery resistance

Design

This pre-intervention and post-intervention clinical trial study will be performed by using permuted randomization using shuffling cards.

Settings and conduct

In this study, 200 pregnant women between the ages of 18 and 40 who refer to the Dr. Mahzad hospital in Urmia for first-trimester screening, by considering the inclusion criteria, will be included in the study. Then, the participants will be subjected to vaginal color Doppler ultrasound of the uterine arteries by a single perinatologist to determine the mean PI and RI of the uterine arteries and will enter the study by increasing the resistance of the uterine arteries. They will be given aspirin and progesterone for 2 weeks. At the end of two weeks, the cervical artery vaginal ultrasound will be performed again and the mean changes in the PI and RI of the uterine arteries after taking the medication will be evaluated.

Participants/Inclusion and exclusion criteria

Mothers who are in the first 3 months of their pregnancy, do not have a history of abortion and are not emergency patients, and also are not pregnant with multiples will be included in the study. Furthermore, individuals with a body mass index greater than 30 kg/m², are allergic to aspirin and progesterone, or have taken aspirin or progesterone in the last week, or have a uterine abnormality or a history of gastrointestinal disease will be excluded from the study.

Intervention groups

The first group will consist of patients who will take progesterone suppositories, the second group will consist of people who will take 80 mg aspirin tablets and the third group will consist of people who will take 160 mg aspirin tablets.

Main outcome variables

Uterine artery resistance indices (RI and PI) and pregnant outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160308026962N5**

Registration date: **2021-12-23, 1400/10/02**

Registration timing: **prospective**

Last update: **2021-12-23, 1400/10/02**

Update count: **0**

Registration date

2021-12-23, 1400/10/02

Registrant information

Name

Tahereh Behrooz Lak

Name of organization / entity

Educational and Treatment Kowsar Center

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 7077

Email address

behroozilak.t@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of progesterone and two different doses of aspirin effect on refusing uterine artery resistance and pregnancy outcome

Public title
Effect of progesterone and aspirin on refusing uterine artery resistance and pregnancy outcome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The patient is in the first 3 months of pregnancy. The women who do not have history of abortion. The women who are not emergency patients. The women who are not pregnant with multiples.
Exclusion criteria:
 Having a body mass index greater than 30 kg/m².
 Having high blood pressure Disagreeing to participate in the study Taking Aspirin in the last week Having Aspirin sensitivity Having Progesterone sensitivity Taking Progesterone in the last week Having a uterine abnormality Having a history of gastrointestinal disease

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be performed using permuted randomization using shuffling cards. In this study, 200 cards with equal ratios (50 cards for each group) will be selected. After merging the cards, a card will be taken out and its allocation will be recorded. After re-merging the cards, another card will be removed. This process continued until a random sequence according to the sample size will be reached.

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 Urmia University of Medical Sciences

Street address

Jahad St., Resalat Blvd., Urmia University of Medical Sciences, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5715833631

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.UMSU.REC1399.402

Health conditions studied

1

Description of health condition studied

Effect of Progesterone and Aspirin on reducing uterine artery resistance and pregnancy outcome

ICD-10 code

ICD-10 code description

Aspirin, Progesterone, uterine artery resistance

Primary outcomes

1

Description

Uterine artery resistance

Timepoint

At the beginning of the study, patients undergoing color Doppler vaginal ultrasounds of the uterine arteries will be placed by a single perinatologist to determine the average PI and RI of the uterine arteries, then they will be given aspirin and progesterone for 2 weeks. At the end of two weeks, the cervical artery vaginal ultrasound will be performed again. The mean changes in the PI and RI of the uterine arteries after taking the medication will be evaluated.

Method of measurement

Checklist before and after intervention

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Progesterone suppository recipient

once a day for two weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: 80 mg Aspirin recipient once a day for two weeks

Category

Treatment - Drugs

3

Description

Intervention group 3: 160 mg Aspirin recipient once a day for two weeks

Category

Treatment - Drugs

4

Description

Control group: Patients did not receive any drugs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mahzad Hospital

Full name of responsible person

Dr. Tahereh Behroozilak

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behroozila.t@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Golizadeh

Street address

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Tahereh Behroozilak

Position

associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Tahereh Behroozilak

Position

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

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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

There is no more information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable