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 take160 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 Behroozi Lak

Name of organization / entity
Educational and Treatment Kowsar Center

Country
Iran (Islamic Republic of)

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Saber Golizadeh

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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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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