Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Effect of low-dose aspirin on uterine artery doppler flow in pregnant women with intrauterine growth retardation

Protocol summary

Study aim
The effect of aspirin on Doppler findings of uterine artery, umbilical cord and midbrain in pregnant women with intrauterine growth retardation

Design
Both the experimental and control groups will be followed up until the end of pregnancy and will undergo Doppler ultrasound at 36 weeks of gestation, and the findings of Doppler ultrasound of the uterine, umbilical and middle cerebral arteries will be compared.

Settings and conduct
In this study, pregnant women undergo biometric ultrasound after 24 weeks of gestation . Mothers with fetuses below the 10th percentile will be included in the biometric ultrasound study. Mothers with fetuses below 10 percent will be randomly divided into control and test groups using a lottery. Prior to any intervention, Doppler ultrasound of the uterine, umbilical and middle cerebral arteries is performed for both test and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Mother's age is less than 40 years. - The mother does not have an underlying disease - is a singleton pregnancy. Have no history of taking aspirin, anoxane, etc. during pregnancy. Do not have preeclampsia and gestational hypertension. - Intrauterine growth restriction is detected before 34 weeks. Exclusion criteria: - Patients do not cooperate to perform serial ultrasounds and do not take aspirin regularly And women will be reluctant to continue reading.

Intervention groups
If there is no improvement in the ultrasound findings of the uterine, umbilical and middle cerebral arteries in the same test group, the aspirin dose will be increased to 150 mg and Doppler ultrasound will be performed again two weeks later.

Main outcome variables
Ultrasound findings of uterine artery, umbilical, middle patient

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180227038892N2**
Registration date: **2022-06-17, 1401/03/27**
Registration timing: **prospective**

Last update: **2022-06-17, 1401/03/27**
Update count: **0**

Registration date
2022-06-17, 1401/03/27

Registrant information
Name
Neda Hashemi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-20, 1401/03/30

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of low-dose aspirin on uterine artery doppler flow in pregnant women with intrauterine growth retardation

Public title

Effect of low-dose aspirin on uterine artery doppler flow in pregnant women with intrauterine growth retardation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The mother should be less than 40 years old. The mother should not have an underlying disease (hypertension, lupus, diabetes, etc.). Have a singleton pregnancy. .... not in pregnancy. Do not have preeclampsia and hypertension. Limit intrauterine growth before 34 weeks.

Exclusion criteria:

- Lack of cooperation of patients to perform serial ultrasounds lack of regular use of aspirin will be the reluctance of women to continue the study.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor and data analyst will not know how the groups are assigned and the study is double-blind. The person who follows the outcome of the disease in patients and the statistician who analyzes the data do not know what medication the patient has received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hazrat Rasool Akram Hospital-Sattar Khan

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-02-05, 1400/11/16

Ethics committee reference number

IR.IUMS.REC.1400.1063

Health conditions studied

1

Description of health condition studied

Doppler improvements of the umbilical artery and midbrain

ICD-10 code

P05.9

ICD-10 code description

Newborn affected by slow intrauterine growth, unspecified

Primary outcomes

1

Description

Doppler improvements of the umbilical artery and midbrain

Timepoint

Follow-up at the end of pregnancy and undergo Doppler ultrasound at 36 weeks of gestation

Method of measurement

Doppler ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant women with fetuses below 10% will be treated with 80 mg of aspirin and will have another Doppler ultrasound two weeks later. If Doppler ultrasound findings improve, the 80 mg dose will be continued until the end of pregnancy. If there is no improvement in the ultrasound findings of the uterine, umbilical and middle cerebral arteries in the same test group, the aspirin dose will be increased to 150 mg and Doppler ultrasound will be performed again two weeks later. Patients in the experimental group will receive doses of aspirin (80 or 150) until the 36th week of pregnancy.

Category

Diagnosis

2

Description
Control group: Mothers with fetuses below the 10% percentile will not receive them without any intervention.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Akram Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Neda Hashemi
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of data like the main outcome or the same will be shared

When the data will become available and for how long

Access after 6 months after publication

To whom data/document is available

Data will be available for all researchers

Under which criteria data/document could be used

It can be used for further research and improvement of surgery. Surgeons and gynecologists can use this data.

From where data/document is obtainable

For receiving data please be contacted with nedahashemi1363@yahoo.com

What processes are involved for a request to access data/document

limitless

Comments