

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Aspirin for prevention of adverse pregnancy outcome in women with elevated alfa-feto protein in second trimester screening,a randomised clinical trial

Protocol summary

Summary

Objective: to evaluate the effect of aspirin(ASA) in prevention of adverse pregnancy outcomes in women with elevated level of alfa-feto protein (AFP) ,in second trimester Down syndrome screening.

Background:elevated level of AFP in second trimester screening is associated with adverse pregnancy outcome such as: pre-eclampcia or intra uterine growth restriction (IUGR).Some studies have reported antiplatelet agents prevent pre-eclampcia and its consequences. Our aim is to evaluate adverse pregnancy outcomes reduction due to aspirin effect. we evaluate the use of second trimester uterine artery doppler to predict adverse pregnancy outcome in women with elevated AFP. Methods:this is a prospective study of women who attend for antenatal care at Imam khomeini hospital of Tehran university of medical sciences. Women with second trimester AFP > 2.5 MOM (which tested in a single reliable labratory), and 16-20 weeks gestation after giving an informed consult are enrolled in the study. Demographic questionnaire is filled. Women are divided into to groups :with or without aspirin with block randomization. Ultrasound scan for fetal anomalies and uterine arteries doppler is done for each people, but the physician is blind of patient group and screen result .Phone calls are made each months till delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203018954N1**

Registration date: **2012-06-05, 1391/03/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-05, 1391/03/16

Registrant information

Name

Sanaz Moosavi

Name of organization / entity

Imam Khomeini hospital, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

tehran university of medical science grant

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-08-20, 1391/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Aspirin for prevention of adverse pregnancy outcome in women with elevated alfa-feto protein in second trimester screening,a randomised clinical trial

Public title

Aspirin for prevention of adverse pregnancy outcome in women with elevated alfa-feto protein

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 16-20 gestational weeks pregnant women who attend Imam khomeini hospital clinic of perinatology, and have a second trimester AFP > 2.5 MOM. They are divided into 2 groups with or without aspirin. Patients are included in study who deliver in Imam khomeini hospital. Exclusion criteria: maternal medical disease and uterus anomalies

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 109

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran university of medical sciences

Street address

Keshavarz blvard, tehran, iran

City

Tehran

Postal code**Approval date**

2012-05-08, 1391/02/19

Ethics committee reference number

89-04-91-12005-53374

Health conditions studied**1****Description of health condition studied**

Elevated level of alfa fetoprotein in second trimester screening

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Preeclampsia

Timepoint

>20 weeks gestation

Method of measurement

BP >= 140/90 and 300 mg protein in 24 hour urine or ++ in a urine analysis

2**Description**

Intrauterine growth restriction

Timepoint

Due to clinical condition evaluate every 4 weeks

Method of measurement

Biometry with sonography and nomograms

Secondary outcomes**1****Description**

NICU admission of neonate

Timepoint

NICU admission after delivery in first 28 days of birth

Method of measurement

hospital records

2**Description**

Neonatal mortality

Timepoint

Mortality of neonate in first 28 day of birth

Method of measurement

Hospital records

3**Description**

Oligohydramnios

Timepoint

>20 weeks gestation

Method of measurement

Ultrasonography

4**Description**

Placenta accreta

Timepoint

In pregnancy

Method of measurement

Clinical or with ultrasonography

5

Description

Hysterectomy

Timepoint

Removal of uterus after delivery

Method of measurement

Clinical

6

Description

Relationship between increased uterine artery pulsatory index and adverse pregnancy outcome

Timepoint

Ultrasonography in 16-20 weeks gestation

Method of measurement

Doppler ultrasound of uterine arteries

Intervention groups

1

Description

aspirin usage

Category

Treatment - Drugs

2

Description

Anomaly scan ultrasonography and routine prenatal care is done

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

imam khomeini hospital

Full name of responsible person

dr sanaz moosavi

Street address

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ms Azvan

Street address

Keshvarz blvard ,Ghods Ave.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Imam khomeini hospital

Full name of responsible person

Dr soghra khazardoost

Position

Asistant professor

Other areas of specialty/work

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Sanaz moosavi

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Other areas of specialty/work

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Postal code

Phone

00

Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty