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

Country

Iran (Islamic Republic of)

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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
Inclusin 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
Preeclampcia
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 moratlity
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
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Asistant professor
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Web page address

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