Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of low dose Aspirin in Prevention of Adverse Pregnancy Outcomes in Women with Unexplained Elevated alpha-protein in second trimester screening

Protocol summary

Summary

The goal of this study is the evaluation of the effect of low dose aspirin (80 milligram) administration, on pregnancy outcome in those complicated with unexplained increased Alpha-fetoprotein. Pregnant women with positive second trimester screening test for Neural Tube Defect (NTD) will included in study and will evaluated via targeted ultrasonography for fetal anomalies, Doppler of uterine arteries, vaginal ultrasonography for cervical incompetency and alpha-fetoprotein retest in maternal serum. Patients with single tone pregnancy and alpha-fetoprotein (AFP) value ≥ 2.50 MoM (multiples of the median) will divided into two groups respect of uterine arteries Doppler (One group with diastolic notch or increased uterine artery resistance (n=100), and another group with normal uterine arteries (n=100)). Each groups will divided into Aspirin treated group (n=50) and control group (n=50) with Random Allocation software. Aspirin will continue until 34 weeks of pregnancy. The outcome of pregnancy on preterm birth, fetal death, preeclampsia, fetal growth restriction (IUGR) and neonatal admission will be considered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042017365N1**
Registration date: **2015-05-05, 1394/02/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-05, 1394/02/15

Registrant information

Name
Fatemeh Bahadori
Name of organization / entity
Urmia University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-07-24, 1393/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low dose Aspirin in Prevention of Adverse Pregnancy Outcomes in Women with Unexplained Elevated alpha-protein in second trimester screening

Public title

Effect of administration low dose aspirin on pregnancy outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with Second-trimester

positive screening test for Neural Tube Defect and alpha-fetoprotein ≥ 2.5 MOM. Exclusion criteria: Women with positive Thrombophili; Thrombocytopenia; Structural or Chromosomal anomalies of the fetus; Placental hematoma; Early severe IUGR; Multiple pregnancies; Ultrasonographic sign of cervical incompetency.

Age
From **18 years** old to **45 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

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
Urmia, Urmia University of Medical Sciences

Street address
Urmia, Urmia University of Medical Sciences

City
Urmia

Postal code

Approval date
2013-08-20, 1392/05/29

Ethics committee reference number
Umsu.rec1390-50

Health conditions studied

1

Description of health condition studied
Preeclampsia

ICD-10 code
014.9

ICD-10 code description
Gestationa l(pregnancy induced) hypertension with significant proteinuria

2

Description of health condition studied
Preterm Labar

ICD-10 code
060.1

ICD-10 code description
Preterm spontaneous labour with preterm delivery

3

Description of health condition studied
IUGR

ICD-10 code
P05.0

ICD-10 code description
Usually referred to as weight below but length above 10th centile for gestational age.

4

Description of health condition studied
Intra Uterine Fetal Death

ICD-10 code
036.4

ICD-10 code description
Intra Uterine Fetal Death

5

Description of health condition studied
Addmision in NICU or Neonatal Ward

ICD-10 code
P01.9

ICD-10 code description
Ernal complication of pregnancy, unspecified

Primary outcomes

1

Description
Neonatal weight respect of gestational age at delivery

Timepoint
Post delivery

Method of measurement
Wight of neonate less than 10 % percentile for gestational age and sign of IUGR

2

Description
Gestational age at delivery

Timepoint
Past delivery

Method of measurement
Birth of neonate before 37 complete weeks

3

Description
Neonatal admision time

Timepoint

Past delivery

Method of measurement

Days of neonatal admission in neonatal ward or neonatal intensive care unit

4

Description

Fetal daeth

Timepoint

Visits in pregnancy

Method of measurement

Non live fetus in uterine period after 20 weeks of gestational age

5

Description

Preeclampsia

Timepoint

Prenatal visits

Method of measurement

Maternal blood presure of>= 140/90 plus proteinuria (>300 milligram in 24 hours urine)

Secondary outcomes

empty

Intervention groups

1

Description

Low dose Aspirin (80 mg) administrated from study time until 34 weeks of pregnancy, compared with control group (no Aspirin)

Category

Treatment - Drugs

2

Description

No additional treatment for control group

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital

Full name of responsible person

Fatemeh Bahadori

Street address

Kowsar center, Motahhari Hospital, Kashani St., Urmia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Ghafarzade Miss

Street address

Research Ward, Setad, Urmia Medical Sciences University

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urmia 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

Urmia University of Medical Sciences

Full name of responsible person

Bahadori Fatemeh

Position

Associate Professore

Other areas of specialty/work

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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