

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

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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

Addmission 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 death

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 pressure of $\geq 140/90$ plus proteinuria (>300 milligram in 24 hours urine)

Secondary outcomes

empty

Intervention groups

1

Description

Low dose Aspirin (80 mg) administered 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

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Bahadori Fatemeh

Position

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Other areas of specialty/work

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