Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effect of Aspirin in pregnancy outcomes in patients with abnormal down syndrome biochemical tests and with normal karyotype

Protocol summary

Summary

The aim of this study is determining the effect of aspirin in pregnancy outcome in pregnant women with abnormal screen tests of Down syndrome and normal karyotype. This is a randomized clinical trial on 85 patients referred to prenatal clinic of Afzalipoor Hospital of Kerman. Inclusion criteria: pregnant women with abnormal biochemical tests in second trimester which have normal karyotype; agreement of the patients. Exclusion criteria: history of sensitivity to aspirin; asthma; Peptic ulcer; renal failure; gout; multifetal pregnancy; gestational diabetes; hemorrhage in first half of pregnancy; maternal disorders; congenital anomalies. In intervention group, 80 mg aspirin (daily) is administered until week 34 of pregnancy. In both groups bilateral uterine artery Doppler is performed by a gynecologist who is blind to groups. Finally the outcomes of pregnancy in all patients is evaluated and collected in data sheet record. The abnormal outcomes of pregnancy are: preterm labor, intrauterine death, intrauterine restricted growth, preeclampsia, Placental abruption, and oligohydramnios.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120620218N1**
Registration date: **2015-01-03, 1393/10/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-03, 1393/10/13

Registrant information

Name

Fatemeh Mirzaee

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Aspirin in pregnancy outcomes in patients with abnormal down syndrome biochemical tests and with normal karyotype

Public title

The effect of Aspirin in pregnancy outcome in patients with abnormal down syndrome blood tests and normal karyotype

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with abnormal biochemical tests in second trimester which have normal karyotype; consent of the patients. Exclusion criteria: history of sensitivity to aspirin; asthma; Peptic ulcer;

renal failure; gout; multifetal pregnancy; gestational diabetes; hemorrhage in first half of pregnancy; maternal disorders; congenital anomalies.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **85**

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
The ethics committee of Kerman University of Medical sciences

Street address
Shafa Square

City
Kerman

Postal code

Approval date
2014-11-29, 1393/09/08

Ethics committee reference number
k/93/299

Health conditions studied

1

Description of health condition studied
pregnancy

ICD-10 code
P00-P96

ICD-10 code description
Fetus and newborn affected by maternal factors and by complications of pregnancy, labour and delivery

Primary outcomes

1

Description
preterm labor

Timepoint
at birthday

Method of measurement
calculated from the number of completed weeks since the first day of the mother's last menstrual period to the date of birth.

2

Description
fetal death

Timepoint
during pregnancy

Method of measurement
examination of fetus

3

Description
Intra uterine Growth Restriction

Timepoint
after delivery

Method of measurement
based on age and weight

4

Description
preeclampsia

Timepoint
every two weeks

Method of measurement
patient visit and blood pressure checking

5

Description
Placental abruption

Timepoint
at birthday

Method of measurement
examination of fetus

Secondary outcomes

1

Description
oligohydramnios

Timepoint
during pregnancy

Method of measurement
examination of fetus

Intervention groups

1

Description
In intervention group: Administration of 80 mg Aspirin tablet daily until 34th week of gestation.
Category
Treatment - Drugs

2

Description
control group: no aspirin administration.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipoor Hospital
Full name of responsible person
Manijeh Assaran
Street address
Afzalipoor Hospital, Zendan Square
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassani
Street address
Tahmasbabad Square, Ebnesina Street
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Manijeh Assaran
Position
Assistant of gynecology
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Person responsible for scientific inquiries

Contact
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Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Mirzai
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Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Manijeh Assaran
Position
Assistant of gynecology
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Phone

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Fax

Email

m.assaran1356@gmail.com

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