Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of enoxaparin and aspirin in women with thrombophilia Pierre mutant genes on the incidence of abortion , low birth weight and placental detachment

Protocol summary

Summary

1-Objectives: The main objective of this study is to determine pregnancy outcome in women with mutant genes thrombophilia 2-Design: 60 women with gestational age of 6 weeks or less that has one or more of the mutant gene that they have least one previous pregnancy that have refered to Al-Zahra hospital in Tabriz, Will be studied 3- Setting and conduct: will be reviewed The women received routine prenatal care during pregnancy and then Will review the abortion;decolman and IUFD 4-Women with 6 weeks gestational and with experienced a previous pregnancy And a mutant gene has been proven in them by PCR. 5-(5) Intervention: LMWH (Clexane) 40 mg subcutaneously every 24 hours and ASA (aspirin) will receive 80 mg every 24 hours . (6) main outcome measures (variables): Primary Outcomes in this study are Detachment of the placenta, low birth weight , preterm birth and abortion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509057676N2**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Simin Taghavi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1553 9161

Email address

taghavisi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research,Tabriz University Of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of enoxaparin and aspirin in women with thrombophilia Pierre mutant genes on the incidence of abortion , low birth weight and placental detachment

Public title

Pregnancy outcome in women thrombophili mutations

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria :All women with homozygous mutations known thrombophilia and abortion or intrauterine death of two or three times or IUFD. Exclusion criteria :Anatomical abnormalities of the uterus and fallopian tubes; Diabetes; Hypothyroidism; PCOS; TORCH; Fetal anomalies; Cancel couples to cooperate with

investigators and anything that causes a lack of access to the mother

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences

Street address
Ethics Committee Of Tabriz University Of Medical Sciences; Third Floor, Central Building of Number2, Golgasht Street

City
Tabriz

Postal code

Approval date
2015-11-25, 1394/09/04

Ethics committee reference number
TBZMED.REC.1394.733

Health conditions studied

1

Description of health condition studied
Genetic disease

ICD-10 code
O28.5

ICD-10 code description
Abnormal chromosomal and genetic finding on antenatal screening of mother

Primary outcomes

1

Description
Decolman

Timepoint
During pregnancy

Method of measurement
Ultrasound

2

Description
Premature birth

Timepoint
During pregnancy

Method of measurement
Physical examination

3

Description
Abortion

Timepoint
From start to 20 weeks

Method of measurement
Physical examination

4

Description
Full-term birth

Timepoint
During pregnancy

Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Case groups : injection of enoxaparin 40 mg subcutaneously every 24 hours.

Category
Treatment - Drugs

2

Description
Case group : ASA(aspirin) 80 mg orally every 24 hours

Category
Treatment - Drugs

3

Description
Control group: non-use of enoxaparin and aspirin

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dr.Simin Taghavi
Street address
Alzahra Hospital, South Artesh Ave
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Alireza Rashidi
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
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,Tabriz 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
Tabriz University Of Medical Sciences
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Dr.Simin Taghavi
Position
Associate Professor of Obstetrics and Gynecology
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Person responsible for updating data

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lahroudin@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