

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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 referred 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)

##### Phone

+98 41 1553 9161

##### Email address

taghavi@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

**Full name of responsible person**

Dr.Simin Taghavi

**Position**

Associate Professor of Obstetrics and Gynecology

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University Of Medical Sciences

**Full name of responsible person**

Dr.Simin Taghavi

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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*