Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of aspirin in compare with heparin plus aspirin in recurrent pregnancy loss treatment

Protocol summary

Summary

To investigate the association between thrombophilia and unexplained recurrent miscarriage (RM) and to evaluate the efficacy of anticoagulant treatment. In this quasi experimental, we enrolled 520 women, who had a history of recurrent miscarriage, which 252 women with unexplained recurrent miscarriage were assigned in this study. Women with chromosomal abnormalities, uterin and cervical anatomical problem, disturb ovarian and hormonal function were excuded from this study. One group received aspirin (80mg daily) for two months before pregnancy and after confirmation of a viable pregnancy until 36 weeks of gestation, and other group received aspirin, as the same, plus heparin (5000unit twice a day) subcutaneously after confirmation of viable pregnancy until 4 weeks after delivery. Type of medication was chosen for each woman according to number of abortion and age. Effectiveness of treatments were evaluated by pregnancy rate till 20 weeks and normal child delivery. Inclusion criteria: unexplained recurrent pregnancy loss; women with thrombophilia exclusion criteria: abnormal karyotypes of each partner; uterine; cervical anatomical disorders on pelvic ultrasonography; hysteroscopy; abnormal ovaries function; abnormal endocrine tests; and antiphospholipid syndrome

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102315123N1**
Registration date: **2013-12-24, 1392/10/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-24, 1392/10/03

Registrant information

Name
Nasrin Ghasemi
Name of organization / entity
Research & Clinical Center for Infertility
Country
Iran (Islamic Republic of)
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ghasemi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and Clinical Center for infertility, Yazd, Iran

Expected recruitment start date

2010-10-01, 1389/07/09

Expected recruitment end date

2012-10-01, 1391/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of aspirin in compare with heparin plus aspirin in recurrent pregnancy loss treatment

Public title

Aspirin and heparin in recurrent pregnancy loss treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: unexplained recurrent pregnancy loss; women with thrombophilia exclusion criteria: abnormal

karyotypes of each partner; uterine; cervical anatomical disorders on pelvic ultrasonography; hysteroscopy; abnormal ovaries function; abnormal endocrine tests; and antiphospholipid syndrome

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **252**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Yazd,

Street address
Bouali Ave, Safaeyeh, Yazd, Iran

City
Yazd

Postal code
8916877391

Approval date
2013-01-16, 1391/10/27

Ethics committee reference number
2460

Health conditions studied

1

Description of health condition studied
recurrent pregnancy loss

ICD-10 code
O03

ICD-10 code description
Spontaneous abortion

Primary outcomes

1

Description
pregnancy after 20 weeks

Timepoint
after 20 weeks

Method of measurement
Sonography

Secondary outcomes

1

Description
Live-birth rates

Timepoint
2 weeks after intervention

Method of measurement
mesearment of blood beta hCG

Intervention groups

1

Description
Intervention: aspirin, 80mg, daily, two month before pregnancy and after pregnancy until 36 weeks of gestation, plus heparin, 5000unit twice a day after pregnancy until 4 weeks after delivery

Category
Treatment - Drugs

2

Description
Control: aspirin orally, 80mg, daily for two month before pregnancy and afte pregnancy until 36 weeks of gestation

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Research and Clinical Center for Infertility, Yazd, Iran

Full name of responsible person
Nasrin Ghasemi

Street address

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research and Clinical Center for Infertility,Yazd, Iran
Full name of responsible person
Alimohammad Abdoli
Street address
Bouali Ave, Safaeyeh, Yazd, Iran
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research and Clinical Center for Infertility,Yazd, Iran
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
Research and Clinical Center for Infertility, Yazd, Iran
Full name of responsible person
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Other areas of specialty/work
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Person responsible for updating data

Contact

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