Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the efficacy of aspirin and low molecular weight heparin in patients with unexplained recurrent spontaneous abortions.

Protocol summary

Summary

The purpose of this study was to evaluate the efficacy of low molecular weight heparin (LMWH) and Aspirin (ASA) on the patients with unexplained recurrent spontaneous abortions (URSA). A total of 100 patients with a history of URSA referring to obstetrics clinic in Shiraz University affiliated hospitals were randomized into two groups. Fifty patients received LMWH (fragmin 5000 unit, subcutaneously, twice a day) as well as ASA 80 mg daily. Another fifty patients received no thromboprophylaxis. Live birth rate, obstetrical complications, prenatal and neonatal complications, and hemorrhagic side effects were recorded and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811073215N1**
Registration date: **2010-05-26, 1389/03/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-26, 1389/03/05

Registrant information

Name

Fatemeh Ahmadpour

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

ahmadpour@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research committee of Shiraz University of Medical Sciences

Expected recruitment start date

2008-10-07, 1387/07/16

Expected recruitment end date

2009-12-22, 1388/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of aspirin and low molecular weight heparin in patients with unexplained recurrent spontaneous abortions.

Public title

The impact of combination thromboprophylaxis on patients with unexplained recurrent spontaneous abortions.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Incidence of at least 3 consecutive recurrent abortions Exclusion criteria: known cause of recurrent abortion, abnorml TFT, FBS, or FSH (3rd day of cycle), uterine anomaly, positive antiphospholipid Ab or anticardiolipin Ab, presence of thrombophilia, abnormal karyotype of both couples

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Committee of Research Ethics of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical sciences, Zand blvd, Nemazi square-beside of Red Crescent-
City
Shiraz
Postal code
71348-14336
Approval date
2008-06-08, 1387/03/19
Ethics committee reference number
87-416

Health conditions studied

1

Description of health condition studied
pregnancy rate beyond 20 weeks of gestational age in habitual aborters
ICD-10 code
O26.2
ICD-10 code description
Pregnancy care of habitual abortor

Primary outcomes

1

Description
continuation of pregnancy beyond 20 weeks of pregnancy
Timepoint
20 weeks after last menstural period
Method of measurement
alive fetus by ob sonography or hearing fetal heart by sonocate or fetoscope

Secondary outcomes

1

Description
live birth rate
Timepoint
after delivery
Method of measurement
live fetus delivery after 28 weeks of gestational age

Intervention groups

1

Description
Low Molecular Weight Heparin, 5000 unit subcutaneous twice a day and Asprin 80 mg po daily till 36 weeks of pregnancy or any premature sign of preterm delivery
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers affiliated to the obstetric's department of Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Ahmadpour
Street address
Zand street,Shahid Faghihi Hospital,Department of ob&gyn
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice canceller for research of Shiraz University of Medical Siences
Full name of responsible person
Dr.Mohammad Hossein Dabaghmanesh
Street address
Zand street-beside red crescent department
City
Shiraz
Grant name
87-4163
Grant code / Reference number
ct-87-4163
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

vice canceller for research of Shiraz University of Medical Siences

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

Department of ob&gyn

Full name of responsible person

Fatemeh Ahmadpour

Position

Resident of ob & gyn/ MD.

Other areas of specialty/work

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Jaleh Zolghadri

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Associate Professor of ob & gyn

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