

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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, abnormal 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 abortors

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 menstrual 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 chancellor for research of Shiraz University of
Medical Sciences

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 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
empty

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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Person responsible for scientific inquiries

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Department of ob&gyn

Full name of responsible person

Jaleh Zolghadri

Position

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