Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Comparative study of therapeutic effect and side effects of enoxaparin with UFH in pregnant patients with mechanical prosthetic heart valves at their first 14 weeks of pregnancy

Protocol summary

Study aim

Comparison of therapeutic effects and complications of enoxaparin with UFH in pregnant patients with mechanical prosthetic heart valves at first 14 weeks of pregnancy

Design

A three phase clinical trial with two intervention groups, in parallel, double-blind, randomized block design, with sample size of 34

Settings and conduct

This study is a double blind clinical trial. The study consisted of all pregnant women at 14 weeks of gestation and having metal heart valve referred to Alzahra and Beheshti Hospital in Isfahan during 1397-1396. The first group received LMVH from the beginning of pregnancy until the end of the first 14 weeks. The second group received UFH in the first, warfarin in the second and UFH in the third trimester. Then newborn weight, type of delivery، gestational age at birth, maternal and fetal complications were evaluated and compared in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No drug allergy to any of the drugs studied, No history of recurrent miscarriage or stillbirth associated with antiphospholipid syndrome, Being monitored by the researcher from the beginning of pregnancy, Having Class I or II heart disease, Having a metal heart valve, Having a pregnancy week of 14 weeks or less Exclusion criteria: Non-cooperation after inclusion, Lack of access to the patient and follow-up, Forced to terminate pregnancy immediately, Warfarin use in the first 3 months, Patients not able to follow up anti-10a factor,Thrombocytopenia (less than 75,000)

Intervention groups

The first group (case) was administered therapeutic dose of LMVH from the beginning of pregnancy until the end of the first 14 weeks, and the second (control) group received UFH in the first trimester, warfarin in the second trimester, and UFH in the third trimester.

Main outcome variables

Newborn weight, type of delivery, gestational age at birth, maternal and fetal complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N28**
Registration date: **2020-01-18, 1398/10/28**
Registration timing: **prospective**

Last update: **2020-01-18, 1398/10/28**
Update count: **0**

Registration date

2020-01-18, 1398/10/28

Registrant information

Name

Sadra Ansaripour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-05, 1398/11/16

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of therapeutic effect and side effects of enoxaparin with UFH in pregnant patients with mechanical prosthetic heart valves at their first 14 weeks of pregnancy

Public title

Comparison of the effect of enoxaparin and UFH in pregnant patients with metallic heart valve at first trimester of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No drug allergy to any of the drugs studied No history of recurrent miscarriage or stillbirth associated with antiphospholipid syndrome Being monitored by the researcher from the beginning of pregnancy Having Class I or II heart disease Having a metal heart valve Having a pregnancy week of 14 weeks or less

Exclusion criteria:

Non-cooperation after inclusion Lack of access to the patient and follow-up Forced to terminate pregnancy immediately Warfarin use in the first 3 months Patients not able to follow up anti-10a factor Thrombocytopenia (less than 75,000)

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible pregnant women were divided into two groups by sequencing site (http://sealedenvelope.com) and divided into two groups using randomized blocking (with 4 blocks) method.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the purpose of blinding, neither the patients nor the researchers were aware of the type of treatment group received until the completion of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City

Isfahan

Province

Isfehan

Postal code

7346181746

Approval date

2019-03-18, 1397/12/27

Ethics committee reference number

IR.MUI.MED.REC.1397.362

Health conditions studied

1

Description of health condition studied

Pregnancy Outcome in Women with Mechanical Prosthetic Heart Valves

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Maternal complications

Timepoint

After intervention

Method of measurement

Check list

2

Description

Fetal complications

Timepoint

After intervention

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, LMWH was administered subcutaneously as 1 mg/kg every 12 hours from the beginning of pregnancy until the end of the first 14 weeks, and then the patient was followed up with anti-factor 10a to achieve the desired therapeutic range.
Category
Treatment - Drugs

2

Description
Intervention group: In this group, UFH was administered in the first trimester, warfarin in the second trimester, and UFH in the third trimester. UFH during initial hospitalization (80 mg / kg stat dose) and then 18 mg / kg infusion. It was repeatedly administered and the dose increased until PTT reached the therapeutic limit. Or subcutaneous discharge of 20,000 to 30,000 UFH per day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Minoo Movahedi
Street address
Soffeh Boulevard
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7346181746
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Farajzadegan
Street address
Isfahan University of Medical Sciences, Hezar jarib Avne
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farajzadegan@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Minoo Movahedi
Position
Professor of gynecology
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available