

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 Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3650 3487

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st_ansari.s@skums.ac.ir

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
Isfahan
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

Minoov Movahedi

Street address

Soffeh Boulevard

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3445 2031

Email

movahedi@med.mui.ac.ir

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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Postal code

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Phone

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Email

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

Minoov Movahedi

Position

Professor of gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Alzahra hospital

City

Isfahan

Province

Isfahan

Postal code

7346181746

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Minoov Movahedi

Position

Professor of gynecology

Latest degree

Specialist

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Minoov Movahedi

Position

Professor of gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics