

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### A clinical trial to compare the effects of heparin with enoxaparin in patients undergoing cesarean section

#### Protocol summary

##### Summary

The main objective of this study is comparing the effects of heparin with enoxaparin in patients after cesarean section. This is a double blind clinical trial on 176 women undergoing cesarean section. Inclusion criteria: The ones who have two of these criteria: age over 35, BMI more than 30, multiparty, preeclampsia, postpartum hemorrhage, emergency cesarean and hysterectomy. Exclusion criteria: patient's discontent, risk of wound infection (diabetes, Chorioamnionitis and long-lasting rupture of the amniotic sac) The subjects are divided into two groups randomly, using simple randomization by means of draw. One group will receive heparin and the other one is given enoxaparin. The patients, the practitioner who gives the drugs and the one responsible for documenting the data are blind to the administered drug. Heparin is given 5000 unit twice daily for 7 to 12 days after surgery. Enoxaparin is prescribed 24 hours following surgery, 40 mg daily for 7 to 10 days. Then the incidence of the signs of deep vein thrombosis, pulmonary emboli and side effects (infection and hematoma) are measured. Wound examination will be done for 10 days following cesarean. The obtained data will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016031427042N1**

Registration date: **2016-04-13, 1395/01/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-13, 1395/01/25

#### Registrant information

##### Name

ZOHREH SALARI

##### Name of organization / entity

KERMAN UNIVERSITY OF MEDICAL SCIENCES

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3322 2250

##### Email address

z\_salari@kmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

KERMAN UNIVERSITY OF MEDICAL SCIENCES

#### Expected recruitment start date

2014-04-21, 1393/02/01

#### Expected recruitment end date

2015-04-21, 1394/02/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A clinical trial to compare the effects of heparin with enoxaparin in patients undergoing cesarean section

#### Public title

The comparison of the side effects of heparin and enoxaparin in patient with cesarean

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: The ones who have two of these criteria: age over 35, BMI more than 30, multiparty, preeclampsia, postpartum hemorrhage, emergency cesarean and hysterectomy. Exclusion criteria: patient's

discontent, risk of wound infection (diabetes, Chorioamnionitis and long-lasting rupture of the amniotic sac)

#### **Age**

No age limit

#### **Gender**

Female

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **176**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Kerman University Medical Sciences

###### **Street address**

Shafa Square

###### **City**

Kerman

###### **Postal code**

###### **Approval date**

2015-12-23, 1394/10/02

###### **Ethics committee reference number**

IR.KMU.afrc.REC.1394.2

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

caesarean section

##### **ICD-10 code**

O82.0

##### **ICD-10 code description**

Delivery by elective caesarean section

### **Primary outcomes**

#### **1**

##### **Description**

Formation of thrombosis in deep veins

##### **Timepoint**

During hospital stay period

##### **Method of measurement**

Clinical examination and Doppler sonography

#### **2**

##### **Description**

Formation of pulmonary embolus

##### **Timepoint**

During hospital stay period

##### **Method of measurement**

Clinical examination and CT scan

### **Secondary outcomes**

#### **1**

##### **Description**

formation of hematoma

##### **Timepoint**

for 10 days after surgery

##### **Method of measurement**

wound examination

#### **2**

##### **Description**

wound infection

##### **Timepoint**

for 10 days after surgery

##### **Method of measurement**

wound examination

### **Intervention groups**

#### **1**

##### **Description**

In intervention group Heparin is given 5000 unit, SC twice daily for 7 to 12 days after surgery

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

In control group Anoxaparin is prescribed 24 hours following surgery, 40 mg, SC daily for 7 to 10 days

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

**Name of recruitment center**

Afzalipoor Hospital

**Full name of responsible person**

Zohre Salari

**Street address**

Zendan Square

**City**

Kerman

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Kerman University of  
Medical Sciences

**Full name of responsible person**

Fatemeh Hassani

**Street address**

Tahmasbabad Square, Ebnesina Street

**City**

Kerman

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Kerman 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**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Zohre Salari

**Position**

gynecologist

**Other areas of specialty/work**

**Street address**

Afzalipoor Hospital, Zendan Square

**City**

KERMAN

**Postal code**

**Phone**

+98 34 3223 5011

**Fax**

**Email**

zohreh\_salari@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Saeede Salari

**Position**

Medical Student

**Other areas of specialty/work**

**Street address**

Afzalipoor Hospital, Zendan Square

**City**

Kerman

**Postal code**

**Phone**

+98 34 3223 5011

**Fax**

**Email**

saeede.salari@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Saeede Salari

**Position**

Medical Student

**Other areas of specialty/work**

**Street address**

Afzalipoor Hospital, Zendan Square

**City**

Kerman

**Postal code**

**Phone**

+98 34 3223 5011

**Fax**

**Email**

saeede.salari@gmail.com

**Web page address**

## 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*