# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Jun 2026

## Investigating the effect of early medical treatment with enoxaparin on the rate of successful fertility following assisted reproductive methods in comparison to assisted reproductive methods without early use of enoxaparin in Kamali Medical Education Center in 1402-1401

## Protocol summary

**Study aim**

Investigating the effect of early medical treatment with enoxaparin on the rate of successful fertility following assisted reproductive methods in comparison to assisted reproductive methods without early use of enoxaparin in Kamali Medical Education Center in 1402-1401

**Design**

Clinical trial with a control group, with parallel groups, single-blind, randomized, phase 3 on 80 patients. For randomization, the block randomization method will be used using: www.sealedenvelope.com

**Settings and conduct**

This study will be done at Kamali hospital in karaj city. Patients underwent IVF at the time of embryo transfer is given subcutaneous enoxaparin . No intervention is performed for the control group. And the rate of chemical pregnancy, clinical pregnancy and Abortion were compared between the two groups.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Age between 20-40 years, BMI body mass index between 18-30, Having an egg suitable for fertilization, Having a suitable endometrium with a diameter greater than 7 mm. Exclusion criteria Not having a specific medical disease that affects the study, Not taking enoxaparin chronically before the study for any reason, Not having a specific coagulation disease such as platelet deficiency, History of previous abortion, History of successful pregnancy.

**Intervention groups**

Control group: There is no intervention. Intervention group: patients undergoing ART at the time of embryo transfer is given subcutaneous enoxaparin at a dose of 1 mg/kg/day/sc, which continues for about two weeks later.

**Main outcome variables**

chemical pregnancy and clinical pregnancy

## General information

**Reason for update**

According to Professor Emar, the number of people participating in the study increased from 80 to 90.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220530055028N1**
Registration date: **2023-01-30, 1401/11/10**
Registration timing: **prospective**

Last update: **2025-09-01, 1404/06/10**
Update count: **1**

**Registration date**

2023-01-30, 1401/11/10

**Registrant information**

**Name**

Mehrnaz Raeisidehkordi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 26 3446 0708

**Email address**

mraeisi283@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-03-11, 1401/12/20

**Expected recruitment end date**

2024-01-10, 1402/10/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of early medical treatment with enoxaparin on the rate of successful fertility following assisted reproductive methods in comparison to assisted reproductive methods without early use of enoxaparin in Kamali Medical Education Center in 1402-1401

**Public title**

Investigating the effect of early medical treatment with enoxaparin on the rate of successful fertility following assisted reproductive methods

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 20-40 years BMI body mass index between 18-30 Having an egg suitable for fertilization Having a suitable endometrium with a diameter greater than 7 mm

**Exclusion criteria:**

Not having a specific medical disease that affects the study. Not taking enoxaparin chronically before the study for any reason Not having a specific coagulation disease such as platelet deficiency History of previous abortion History of successful pregnancy

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Our sample size is 90 people, with 45people in each group. Block randomization method was designed by epidemiologist using STATA version 13 software. Unit of randomization such is individual. The number of blocks considered is 4.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

90 cards containing sequences of treatments will be written and a10-digit random code, as the patient’s identification number, will be provided for each packet. When the researcher announces the eligibility of a patient, the methodologist will provide the researcher with the envelope. The person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. Data analysis will be carried out by a statistician who is aware of all the processes performed.the participants are aware of the type of intervention

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

**Street address**

Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Approval date**

2022-12-03, 1401/09/12

**Ethics committee reference number**

IR.ABZUMS.REC.1401.258

## Health conditions studied

### 1

**Description of health condition studied**

Infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

## Primary outcomes

### 1

**Description**

Chemical pregnancy

**Timepoint**

14 days after embryo transfer

**Method of measurement**

Serum BhCG level

### 2

**Description**

Clinical pregnancy

**Timepoint**

5 weeks after transfer

**Method of measurement**

Sonography

## Secondary outcomes

### 1

**Description**
Abortion
**Timepoint**
Before the 20th week of pregnancy
**Method of measurement**
Sonography

## Intervention groups

### 1

**Description**
Intervention group: The intervention group of patients undergoing ART at the time of embryo transfer is given subcutaneous enoxaparin at a dose of 1 mg/kg/day/sc, which continues for about two weeks later.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: There is no intervention.
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Kamali hospital
**Full name of responsible person**
Mehrnaz Raeisidehkordi
**Street address**
Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street
**City**
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mraeisi283@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Karaj University of Medical Sciences
**Full name of responsible person**
Mohammad Nourisepehr
**Street address**
Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
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**Phone**
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**Email**
Research@abzums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Karaj 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**
Karaj University of Medical Sciences
**Full name of responsible person**
Mehrnaz Raeisidehkordi
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Gynecology and Obstetrics
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## Person responsible for scientific inquiries

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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