

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of Efficacy and Safety of Enoxaparin in Treatment of Vascular Intra-Uterine Growth Retardation: A Randomized Clinical Trial

Protocol summary

Study aim

Role of enoxaparin in augmenting the intra-uterine growth in patients with vascular intra-uterine growth retardation

Design

Non-blinded, non-placebo controlled, randomized clinical trial with a sample size of 126 patients

Settings and conduct

This study will be carried out in a tertiary level referral hospital. Women aged >18 years old with singleton pregnancy and diagnosis of intra-uterine growth retardation are randomly allocated to 2 groups. In control group patients receive the routine standard treatments for intrauterine growth retardation. In intervention group, patients receive 4000 IU of enoxaparin daily as SC.

Participants/Inclusion and exclusion criteria

All >18 years old women with singleton pregnancy and diagnosed intra-uterine growth retardation

Intervention groups

4000 IU enoxaparin SC daily

Main outcome variables

Neonatal birth weight

General information

Reason for update

Acronym

IUGR: Intra-Uterine Growth Retardation

IRCT registration information

IRCT registration number: **IRCT20180819040830N4**

Registration date: **2020-05-01, 1399/02/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-01, 1399/02/12**

Update count: **0**

Registration date

2020-05-01, 1399/02/12

Registrant information

Name

Zahra Naeiji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 2628

Email address

z.naeigi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-26, 1398/10/05

Expected recruitment end date

2020-05-24, 1399/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Efficacy and Safety of Enoxaparin in Treatment of Vascular Intra-Uterine Growth Retardation: A Randomized Clinical Trial

Public title

Enoxaparin in Treatment of Vascular Intra-Uterine Growth Retardation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

>18 years old women with singleton pregnant women
Diagnosis of intra-uterine growth retardation for their fetus

Exclusion criteria:

Maternal age <18 years old Multiple pregnancy

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Computer-generated block of 4, block randomization

Blinding (investigator's opinion)

Not 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 Tehran University of Medical Sciences

Street address

Qods St., Bolvar Keshavrz Blv.

City

Tehran

Province

Tehran

Postal code

13354234

Approval date

2019-12-23, 1398/10/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.683

Health conditions studied

1

Description of health condition studied

Intra-uterine growth retardation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Birth weight

Timepoint

At delivery time

Method of measurement

Measuring neonatal birth weight by an electronic scale

Secondary outcomes

1

Description

Enoxaparin side effects (including active bleeding due to enoxaparine use or thrombocytopena after beginning the enoxaparin

Timepoint

Any time after beginning the study

Method of measurement

History taking, physical exam, laboratory test

Intervention groups

1

Description

Intervention group: 4000 IU per day SC enoxaparin

Category

Treatment - Drugs

2

Description

Control group: routine care

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiye hospital

Full name of responsible person

Zahra Naeiji

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Shishegar Khane St., Fadayian Eslam Blv. Shoosh Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahrayian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Naeiji

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available