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 enoxaparine 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 pregnanvy

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

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

City
Tehran

Province
Tehran

Postal code
1445763693

Phone
+98 21 5506 2628

Email
zahranaeiji98@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahrayian
Street address
Qods St., Bolvar Keshavarz Blv.
City
Tehran
Province
Tehran
Postal code
13354234
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
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
Street address
Shishegar Khane St., Fadayian Eslam Blv. Shoosh Sq.
City
Tehran
Province
Tehran
Postal code
1445763693
Phone
+98 21 5506 2628
Email
zahranaeiji98@yahoo.com

Person responsible for scientific 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
Street address
Shishegar Khane St., Fadayian Eslam Blv. Shoosh Sq.
City
Tehran
Province
Tehran
Postal code
1445763693
Phone
+98 21 5506 2628
Email
zahranaeiji98@yahoo.com

Person responsible for updating data

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
Street address
Shishegar Khane St., Fadayian Eslam Blv. Shoosh Sq.
City
Tehran
Province
Tehran
Postal code
1445763693
Phone
+98 21 5506 2628
Email
zahranaeiji98@yahoo.com

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