

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Therapeutic Effects of Heparin on Treatment of chronic diabetic foot ulcers: a randomized blind controlled clinical trial

Protocol summary

Summary

Objectives: To determine the effect of heparin therapy on healing chronic wound of diabetic foot in diabetic patients hospitalized in Rasht Razi hospital Design: In a single-blind randomized controlled clinical trial on 136 patients with chronic diabetic foot ulcers referred to Razi Hospital clinics will be enrolled in the study. The patients with inclusion criteria were randomly divided into two groups of 68 subjects. They will be unaware of the allocation of the two groups. Setting and conduct: Diabetic patients will be evaluated in terms of chronic diabetic foot ulcers, and if they have medically approved chronic diabetic foot ulcers, they will be reviewed in inclusion and exclusion criteria. Participants including major eligibility criteria Inclusion criteria: 1. Recent chronic neuropathic wounds in diabetic foot (less than 10 days) 2. wound with degree 1 based on Wegener scale or debrided or limited amputated patients with degree 2, 3 and 4 3- ABI<0.9 (without ischemic or neuroischemic diabetic foot ulcer) 4. Open wound or debrided or limited amputated patients Exclusion criteria: 1.The existence of chronic diabetic foot ulcers caused by ischemia 2-The patient under treatment with anticoagulant therapy at the time of enrollment 3-Contraindications in low molecular weight heparin administration, including severe renal impairment, liver failure Child-Pugh class B or C, having bleeding disorders and proliferative diabetic retinopathy of bleeding risk Interventions: Daily injection of low molecular weight heparin injections of 40 mg for 30 days Main outcome: Diabetic foot ulcers

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120130508N2**

Registration date: **2017-04-05, 1396/01/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-05, 1396/01/16

Registrant information

Name

Hosein Hemmati

Name of organization / entity

Vascular surgery and dialysis research center, Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 13 3354 2460

Email address

hemmati@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

state

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic Effects of Heparin on Treatment of chronic diabetic foot ulcers: a randomized blind controlled clinical trial

Public title

Heparin Effect on Diabetic Foot Ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria 1- Recent chronic neuropathic diabetic foot ulcer (less than 10 days) 2- Ulcer Wagner grade is 1 or debrided patients or limited amputation with Wagner grade of 2, 3, and 4 3- ABI > 0.9 (not ischemic and neuroischemic) 4- Open or debrided ulcer or limited amputation 5- Having informed consent for study
Exclusion Criteria 1- Chronic diabetic foot ulcers caused by ischemia 2- Under treatment with anticoagulant therapy at the time of study inclusion 3- contraindication of low molecular weight heparin administration, including severe renal failure (creatinine lower than 30 ml/min (hepatic failure of Child-Pugh class B or C, having bleeding disorders and proliferative diabetic retinopathy subject to bleeding risk 4- Active osteomyelitis 5- Systemic sepsis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Random Numbers Table produced by computer

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

GUMS Research and Technology Deputy building

City

Rasht

Postal code

Approval date

2016-11-08, 1395/08/18

Ethics committee reference number

IR.GUMS.REC.1395.265

Health conditions studied

1

Description of health condition studied

Chronic Diabetic Foot Ulcer

ICD-10 code

E 10.6

ICD-10 code description

Insulin-dependent diabetes mellitus with other specified complications

Primary outcomes

1

Description

Diabetic Foot Ulcer

Timepoint

every 10 days in 30-day period

Method of measurement

Digital imaging

Secondary outcomes

empty

Intervention groups

1

Description

Study group: Daily injection of 40 mg of low-molecular weight heparin during 30 days

Category

Treatment - Drugs

2

Description

Control group: Daily injection of 0.2 ml of normal saline during 30 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Razi Hospital

Full name of responsible person

Dr. Milad Sarrafi

Street address

Razi Hospital

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Street address

Guilan University of Medical Sciences

City

Rasht

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Dr Milad Sarrafi

Position

Physician

Other areas of specialty/work**Street address**

Razi Hospital

City

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Hossein Hemmati

Position

Associate Professor - Fellowship in Vascular Surgery

Other areas of specialty/work**Street address**

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hemmati@gums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Hossein Hemmati

Position

Associate Professor - Fellowship in Vascular Surgery

Other areas of specialty/work**Street address**

Razi Hospital

City

Rasht

Postal code**Phone**

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Fax**Email**

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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