

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effect of Pentoxifylin in treatment of diabetic foot ulcers

Protocol summary

Summary

In a Double-Blind RCT for evaluation of Pentoxifylin effect on Diabetic foot ulcer, 22 patients with foot ulcers (grade 1 & 2 Wagner classification) were enrolled into two groups. Intervention group received Pentoxifylin 400 mg/day and control group received placebo. Patients were followed for 3 months and compared in terms of rate of healing, side effects and need to debridement or amputation. Patients were excluded from the study if amputation or debridement needed. Patients were also identical in terms of blood sugar and nutritional state (HbA1C one unit upper than upper limit, Alb more than 3.5). Patients who had peripheral vascular disease, history of consumption of drugs that may influence wound healing or coagulation system, contraindications for Pentoxifylin (Ischemic heart diseases, Retinal hemorrhage, and Cerebral hemorrhage) were excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708041399N1**

Registration date: **2009-04-28, 1388/02/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-04-28, 1388/02/08

Registrant information

Name

Setareh Soltany

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2005-07-21, 1384/04/30

Expected recruitment end date

2006-07-21, 1385/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Pentoxifylin in treatment of diabetic foot ulcers

Public title

Evaluation of the effect of Pentoxifylin in treatment of diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Presence of NIDDM (Non insulin dependent diabetes mellitus), presence of foot ulcer, HbA1C one unit more than normal range. Exclusion Criteria: Serum Alb<3.5 mg/dL, presence of peripheral vascular disease, non-palpable Dorsalis pedis & Tibialis posterior pulses, consumption of Glucocorticoids and Warfarin, contraindication for Pentoxifylin.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 22

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan university of medical sciences

Street address

Basij blvd., Semnan

City

Semnan

Postal code

Approval date

2005-05-30, 1384/03/09

Ethics committee reference number

182

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E11.5

ICD-10 code description

Non-insulin-dependent diabetes mellitus With peripheral circulatory complications

Primary outcomes

1

Description

Healing of diabetic foot ulcer

Timepoint

Baseline, every one month for 3 months

Method of measurement

Decrease of the wound size relative to original size:
length in Linear wounds (mm), surface in planar wounds

(mm²), volume in 3 dimensional wounds (mm³)

Secondary outcomes

1

Description

Drug adverse effects

Timepoint

3 months

Method of measurement

Clinical manifestations of Dizziness or Retinal hemorrhage

2

Description

Need to debridement

Timepoint

3 Months

Method of measurement

proportion of patients who need debridement

3

Description

Need to amputation

Timepoint

3 months

Method of measurement

proportion of patients who need amputation

Intervention groups

1

Description

Pentoxifyline (Oral capsule, 400 mg, BID for 3 months)

Category

Treatment - Drugs

2

Description

Flour filled capsules as placebo(Oral capsule like Pentoxifylin, BID for 3 months)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital of Semnan

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan university of medical science

Full name of responsible person

Dr Raheb Ghorbany

Street address

Iran, Semnan, Basij boulevard, Central setad of University

City

Semnan

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

Yes

Title of funding source

Semnan university of medical science

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**

Semnan University of Medical Sciences

Full name of responsible person

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Position

Assistant professor of surgery, General surgeon

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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