Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Summary

In a Double-Blind RCT for evaluation of Pentoxyphilin effect on Diabetic foot ulcer, 22 patients with foot ulcers (grade 1 & 2 Wagner classification) were enrolled into two groups. Intervention group received Pentoxyphilin 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 debridment or amputation. Patients were excluded from the study if amputation or debridment 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 Pentoxyphilin (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

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Name of organization / entity

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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 Pentoxyphilin in treatment of diabetic foot ulcers

Public title

Evaluation of the effect of Pentoxyphilin 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 Pentoxyphilin.

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 (mm^2), volume in 3 dimensional wounds (mm^3)

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 debridment

3

Description
Need to amputation
Timepoint
3 months
Method of measurement
proportion of patients who need amputation

Intervention groups

1

Description
Pentoxyphiline (Oral capsule, 400 mg, BID for 3 months)
Category
Treatment - Drugs

2

Description
Flour filled capsules as placebo(Oral capsule like Penthoxyphilin, 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 boulvard, 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

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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