

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of pentoxifyllin and its compration with placebo as an adjunctive drug in diabetic foot ulcer in diabetic patients.

Protocol summary

Summary

This study is double blind. Placebo control and done in razi hospital of Ahwaz. Target of study is effect of pentoxifyllin as an adjunctive drug in antibiotic treatment of diabetic foot infection. The patients with diabetic foot ulcer, grade 2 and 3 wagner come to the study and those patients with upper GI upset, Sensitivity of pentoxifylline 3-Sensitivity to methylxanthines and Limb vascular occlusion more than 80 percent were excluded from the study. All of the patients are eighty divided into two groups randomly. In interventional group tab Pentoxifylline 400mg are administered every eight hours for 6 Month. In placebo group, placebo drugs are administered every eight hours for 6 Month. Then the patients are visited weekly in first month then monthly for 6 month. In each visit we evaluated the patients for: clinical status, ankle/brachial index, decrease of ulcer size and need to ulcer debridement, foot amputation, change or discontinuation of antibiotics. Finally, we analyse and compare the placebo and drug groups data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122411872N1**

Registration date: **2013-02-24, 1391/12/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-24, 1391/12/06

Registrant information

Name

Hassan Barabadi

Name of organization / entity

Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

School of Medicine, Jundishapur University of Medical Sciences

Expected recruitment start date

2013-01-04, 1391/10/15

Expected recruitment end date

2013-07-06, 1392/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pentoxifyllin and its comparison with placebo as an adjunctive drug in diabetic foot ulcer in diabetic patients.

Public title

Effect of pentoxifyllin in diabetic foot

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Diabetic patients with diabetic foot ulcer grade 2 and 3 wagner exclusion criteria: dyspepsia; sensitivity to pentoxifylline; Sensitivity to methylxanthines; limb vascular occlusion more than 80 percent.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Not 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

School of Medicine, Ahwaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Golestan Street -

City

Ahwaz

Postal code

61355393

Approval date

2012-10-27, 1391/08/06

Ethics committee reference number

eth-608

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

2

Description of health condition studied

Diabetes

ICD-10 code

E14

ICD-10 code description

Unspecified diabetes mellitus

3

Description of health condition studied

diabetes

ICD-10 code

E12

ICD-10 code description

Malnutrition-related diabetes mellitus

4

Description of health condition studied

diabetes

ICD-10 code

E13

ICD-10 code description

Other specified diabetes mellitus

5

Description of health condition studied

diabetes

ICD-10 code

E11

ICD-10 code description

non-Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Healing of diabetic foot ulcers

Timepoint

weekly in first month then every month up to six months

Method of measurement

CM and MM

Secondary outcomes

1

Description

ankle/brachial index improvement

Timepoint

weekly in first month then every month up to six months

Method of measurement

with sphingomanometry and with mmHg unit

2

Description

Amputation need

Timepoint

weekly in first month then every month up to six months

Method of measurement

with physical exam , need or dont need

3

Description

debridmeant need

Timepoint

weekly in first month then every month up to six months

Method of measurement

with physical exam, need or dont need

Intervention groups

1

Description

for intervention group; tab Pentoxifylline 400mg every eight hours for 6 Month.

Category

Treatment - Drugs

2

Description

for control group;placebo every eight hours for six month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ahwaz Razi hospital

Full name of responsible person

Barabadi Hassan Dr

Street address

Razi hospital, West Beach Blvd, Ahwaz

City

Ahwaz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Diabetes Research Center, Ahwaz Jundishapur Medical School

Full name of responsible person

Fegghi Dr

Street address

Diabetes Research Center, Ahwaz Jundishapur Medical School, Golestan street, Ahwaz

City

ahwaz

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

Yes

Title of funding source

Diabetes Research Center, Ahwaz Jundishapur Medical School

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**

Jundishapur University of Medical Sciences

Full name of responsible person

Barabadi Hassan

Position

Resident of Internal Medicine

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

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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