Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The evaluation of the effect of pentoxifylline on lower extremity blood flow in high-risk diabetic patients for diabetic foot ulcers using muscle perfusion scan byTc99m-MIBI in a pilot study

Protocol summary

Study aim

The evaluation of changes and improvement of lower extremity perfusion after pentoxifylline administration using qualitative and quantitative criteria. Tc99m-MIBI in diabetic patients at high risk of developing a diabetic foot ulcer.

Design

Clinical trial without a control group, the single group receiving an intervention, without blinding, phase 2, 18 patients

Settings and conduct

After receiving oral pentoxifylline treatment with a dose of 400 mg twice a day for 4-6 weeks, the perfusion was re-scanned with the same initial protocol to evaluate the response to treatment and lower extremity perfusion changes, in the nuclear medicine department of Imam Khomeini Hospital with Tc 99m-MIBI. Qualitative data (visual comparison of exercise-stressed limb activity with the opposite limb) and quantitative data (determination of blood supply: measuring the amount of count in the rectangular ROI on the stressed limb with the opposite limb) were compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a history of at least 5 years of diabetes Male patient Exclusion criteria: History of diabetic foot ulcer History of macro or microvascular complications of diabetes (proliferative retinopathy, myocardial infarction, stroke, kidney failure requiring dialysis) Patient dissatisfaction with enrollment Impossibility of dorsal and plantar flexion of foot History of any injury, tumor, or other diseases in the lower extremities

Intervention groups

Oral administration of 400 mg twice a day for 4-6 weeks

Main outcome variables

Improvement of perfusion in the lower extremities followed by receiving pentoxifylline using qualitative indicators (comparing the activity of the limb under flexion-extension stress with the opposite limb) and quantitative indicators Muscle perfusion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040823N1**
Registration date: **2020-12-19, 1399/09/29**
Registration timing: **retrospective**

Last update: **2020-12-19, 1399/09/29**
Update count: **0**

Registration date

2020-12-19, 1399/09/29

Registrant information

Name

Mehrshad Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-19, 1397/12/28

Expected recruitment end date

2020-03-01, 1398/12/11

Actual recruitment start date

2019-03-19, 1397/12/28

Actual recruitment end date
2020-03-01, 1398/12/11
Trial completion date
2020-03-01, 1398/12/11

Scientific title
The evaluation of the effect of pentoxifylline on lower extremity blood flow in high-risk diabetic patients for diabetic foot ulcers using muscle perfusion scan byTc99m-MIBI in a pilot study

Public title
The evaluation of the effect of pentoxifylline on diabetic foot ulcers
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being Diabetic for more than 5 years male patients Candidate for pentoxifylline based on endocrinologist diagnosis
Exclusion criteria:
History of diabetic foot ulcer patient dissatisfaction with enrollment History of macro or microvascular complications of diabetes (proliferative retinopathy, myocardial infarction, stroke, renal failure requiring dialysis) Impossibility of dorsal and plantar flexion of the foot History of any trauma, tumor or other disease in the lower extremities
Age
No age limit
Gender
Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **18**
Actual sample size reached: **18**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran university of Medical Science
Street address
research office, 1st floor, block NO1 of medical science faculty, Poorsina St , Qods St, Enghelab Sq.
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2019-03-17, 1397/12/26
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.959

Health conditions studied

1

Description of health condition studied
Diabetes mellitus
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Increased perfusion reserve of the lower extremities
Timepoint
Imaging was performed at the beginning of the study (before the intervention) and 4 to 6 weeks after taking the Medication.
Method of measurement
Gamma camera imaging

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A group of 18 people received 400 mg of pentoxifylline twice daily for 4 - 6 weeks. Imaging of the lower extremities was performed before and after the period of medication administration by gamma camera of ADAC device.
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinologist's office

Full name of responsible person
Dr. Alireza Esteghamati

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Motahhari St. - Before Dr. Shariati - Ibn Sina Building - Second Floor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammadali Sahraiyan

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Keshavarz Boulevard, Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

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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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mehrshad Abbasi

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Nuclear Medicine

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The sharable data in addition to the quantitative and qualitative analysis performed is before and after medication images which be will be share deidentified.
When the data will become available and for how long
The access period will start 6 months after the results are published
To whom data/document is available
Both academics and non-faculty medical staff will be able to use it.
Under which criteria data/document could be used
The deidentified images of the patient will be available to the principal investigator and can be used by people who need access.
From where data/document is obtainable
Applicants can contact the principal researcher by email for more information and data than published in the form of articles and also before and after taking the medication images.
What processes are involved for a request to access data/document
For more information, after sending the e-mail, an initial response will be given up to 24 hours later, and according to the type of applied information, they will be provided to the applicant up to 1 month after the initial e-mail.
Comments