Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Randomized Double-Blind Placebo-Controlled Trial of ANGIPARS (TM) in Diabetic Foot Ulcer

Protocol summary

Summary

In this randomized double-blind placebo controlled trial, a total of 300 participants (150 in each of the two arms) will be recruited from a tertiary clinic in Tehran. The patients are aged between 18 and 75 years and are diagnosed with grade II or III foot ulcer based on the Wagner wound classification. The closure of the wound surface area is determined as the primary outcome, whereas the secondary outcome consists of ankle brachial index, toe pressure, wound temperature and the adverse effects of Angipars. These factors will be measured at baseline as well as 2, 4, 6, 10 and 18 weeks after the treatment by an individual unaware of the participants' baseline characteristics and their treatment allocation. We will also collect data and analyze intention-to-treat of our intervention. The results of this study will provide valuable new information regarding Angipars, a novel herbal drug hypothesized to be effective in treating diabetic foot ulcers (DFU).

General information

Acronym

ADFU

IRCT registration information

IRCT registration number: **IRCT138806111414N2**
Registration date: **2010-03-16, 1388/12/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-03-16, 1388/12/25

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0037

Email address

emrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

1) Endocrinology and Metabolism Research Center(EMRC) of Tehran University of Medical Sciences, 2) ParsRoos Company

Expected recruitment start date

2010-08-01, 1389/05/10

Expected recruitment end date

2012-08-01, 1391/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized Double-Blind Placebo-Controlled Trial of ANGIPARS (TM) in Diabetic Foot Ulcer

Public title

Effects of ANGIPARS in Diabetic Foot Ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria •Diagnosis of Diabetes Mellitus (Type 1 or 2) defined by the American Diabetes Association criteria •Age equal or more than 18 years and less than 75 •Presence of one or more grade II or III foot ulcers based on the Wagner wound classification more than one square centimiter, for at least 2 weeks. Infection should

be treated successfully prior to recruitment •Haemoglobin A1C less than 10% •Signing a written informed consent Exclusion criteria •Receiving any investigational drug within the last 30 days •Severe Peripheral Arterial Diseases (PAD), (Ankle Brachial Pressure index less than 0.5) •Any local or systemic signs of active infection including purulent discharge or marginal skin erythema (up to three centimetres from the margin of the wound) •Presence of acute osteomyelitis or exposed bone •Presence of any other systemic or chronic illness such as: oChronic hepatic diseases oChronic Kidney Diseases (GFR <60 ml/min per 1.73 m2) oClinically complicated pulmonary, cardiac, hematologic, gastrointestinal diseases, oAny other endocrine diseases other than DM oSerious psychological problems such as severe anxiety or depression •Malignancy •Pregnancy or intention to become pregnant during the study period (4.5 months) •Inability to give an informed consent •Corticosteroid therapy •Any drug hypersensitivity •Radiotherapy, Chemotherapy or the use of any immunosuppressive drugs •Electrolyte imbalance •Alcohol or substance misuse

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Endocrinology & Metabolism Research Center

Street address
5th Floor, Doctor Shariati Hospital, North Kargar Avenue

City
Tehran

Postal code
1411413137

Approval date
2009-08-15, 1388/05/24

Ethics committee reference number
E-0058

Health conditions studied

1

Description of health condition studied
Diabetic Foot Ulcer

ICD-10 code
E10.5

ICD-10 code description
Insulin-dependent diabetes mellitus, With peripheral circulatory complications

2

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
Wound surface area

Timepoint
Baseline, weeks 2, 4, 6, 10, and 18

Method of measurement
To determine this outcome, a ruler will be placed at the wound margin and then digital photograph will be taken and the wound surface area will be determined using special software (Hakim Software) through planimetry methods

Secondary outcomes

1

Description
Ankle Brachial Index (ABI)

Timepoint
Baseline, weeks 2, 4, 6, 10, and 18

Method of measurement
Ratio

2

Description
Toe pressure
Timepoint
Baseline, weeks 2, 4, 6, 10, and 18
Method of measurement
mmHg(by fastening a small calf around the toe and measuring the capillary pressure by PPGI probe using arterial Doppler sonography)

3

Description
Wound bed temperature
Timepoint
Baseline, weeks 2, 4, 6, 10, and 18
Method of measurement
Centigrade(by DermaTemp)

4

Description
Patient Global Impression of Change (PGIC)
Timepoint
Baseline, weeks 2, 4, 6, 10, and 18
Method of measurement
Through a 10-point scale (P&CGIC-Form)

5

Description
Quality of life
Timepoint
Baseline, weeks 2, 4, 6, 10, and 18
Method of measurement
SF-12 HEALTH SURVER (Iranian Version)

6

Description
Clinical Global Impression of Change (CGIC)
Timepoint
Baseline, weeks 2, 4, 6, 10, and 18
Method of measurement
Through a 10-point scale(P&CGIC-Form)

7

Description
Clinical assessment of advers event
Timepoint
Baseline, weeks 2, 4, 6, 10, and 18
Method of measurement
Adverse Event Report Form

Intervention groups

1

Description
Angipars 1 capsule, 100 mg bid in addition to 3% topical cream bid for a period of 6 weeks in addition to standard wound care (glycemic control , debridement, dressing, offloading and infection control)
Category
Treatment - Drugs

2

Description
Placebo, the same drug preparations contained inert substances, with the same dosage and administration route as intervention group in addition to standard wound care
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetic and Metabolic Center of Tehran affiliated to Endocrinology and Metabolism Research Center
Full name of responsible person
Mashayekh Bakhshi F
Street address
Cross Heyat St., Shahrivar Avenue, North Kargar St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Endocrinology and Metabolism Research Center(EMRC) of Tehran University of Medical Sciences
Full name of responsible person
Heshmat R
Street address
5th Floor, Doctor Shariati Hospital, North Kargar St.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Endocrinology and Metabolism Research Center(EMRC) of Tehran University of Medical Sciences
Proportion provided by this source
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

2

Sponsor

Name of organization / entity
ParsRoos Company

Full name of responsible person
Madani S.H.

Street address
No. 568,13th alley, Hormozan st., Sahrak-e-Ghods

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
ParsRoos Company

Proportion provided by this source

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Endocrinology and Metabolism Research Center of Tehran University of Medical Sciences

Full name of responsible person
Larijani B

Position
Endocrinologic Subspecialist

Other areas of specialty/work

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th Floor, Doctor Shariati Hospital, North Kargar St.

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http://vcemrc.tums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Endocrinology and Metabolism Research Center of Tehran University of Medical Sciences(EMRC of TUMS)

Full name of responsible person
Heshmat R

Position
Research Deputy of EMRC / Epidemiologist

Other areas of specialty/work

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Email
rheshmat@razi.tums.ac.ir

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