Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Topical Myrtus Communis Product on Diabetic Foot Ulcer; A Pilot Study

Protocol summary

Summary

This is a double blind study, for assessing the effect of topical myrtle extract (6%) and placebo (Gel base) in the treatment of diabetic foot ulcer. 20 diabetic patients with grade I or II, stage A foot ulcers (according to the Texas University Wound Classification System) voluntarily are enrolled. The patients are randomly divided to two groups of intervention and placebo by the random number table; standard treatment (dressing properly +control blood sugar + off-loading) with local myrtle product, or standard treatment with placebo for 8 weeks. If necessary, surgical debridement of wounds will be performed at the first visit and at follow-up visits. Drug or placebo will be applied topically once daily. Wound sizes at the beginning and at the end of each week will be measured. Before entering the study, the required information is taken by the project agent and after receiving a written signed consent form and demographic questionnaire is filled. At the end of the study, relevant information is extracted and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022126684N1**
Registration date: **2016-07-31, 1395/05/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-31, 1395/05/10

Registrant information

Name

Seyed Ali Khodaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3728 0215

Email address

sa.khodaei@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahed University

Expected recruitment start date

2016-07-30, 1395/05/09

Expected recruitment end date

2016-11-29, 1395/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Topical Myrtus Communis Product on Diabetic Foot Ulcer; A Pilot Study

Public title

Effect of Myrtle on Diabetic Foot Ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age 18 years old and more; type 1 or 2 diabetes with glysemin control; have dorsalis pedis and posterior tibial pulses; ulcer size ≥ 1 cm2; grade IA or IIA according to Texas University Foot Wound Classification System. Exclusion criteria: clinical infection at the studied ulcer site; clinically significant lower-extremity ischemia (ABI< 0.65); nondiabetic ulcer; active Charcot’s disease; hypersensitivity to any drugs; pregnant or lacting woman; any sever disease that may impair wound healing (sever hepatic disease and cirrhosis,

connective tissue diseases, malignancy, treatment with dialysis, vasculitis, immune system disorders); immunosuppressive agents; chemotherapy or radiation therapy; current abuse of alcohol or other substances; HbA1c>10%; serious psychological problems.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
Shahed University

Street address
Opposite of Imam Khomeiny shrine, Tehran-Qom Freeway

City
Tehran

Postal code

Approval date
2016-02-22, 1394/12/03

Ethics committee reference number
IR.Shahed.REC.1394.97

Health conditions studied

1

Description of health condition studied
Diabetic Foot Ulcer

ICD-10 code
E14.5

ICD-10 code description
Unspecified diabetes mellitus with peripheral circulatory complications

Primary outcomes

1

Description
Wound surface area

Timepoint
weekly

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 through planimetry methods

Secondary outcomes

1

Description
Clinical assessment of advers event

Timepoint
weekly

Method of measurement
Adverse Event Report Form

Intervention groups

1

Description
Treatment of diabetic foot ulcers with myrtle product(6%) topically once daily for 8 weeks

Category
Treatment - Drugs

2

Description
Treatment of diabetic foot ulcers with placebo(base gel) topically, once daily for 8 weeks

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
Seyed Ali Khodaie

Street address
5th Floor, Shariati Hospital, North Karegar street

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahed University
Full name of responsible person
Dr. Mohsen Naseri
Street address
No.1471, Between Forsat and Nosrat St, North Kargar Ave
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahed University
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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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