

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of Pistachio (mutica or atlantica) in improvement of diabetic foot

Protocol summary

Summary

Diabetes is an increasing health problem in the modern countries. Diabetic foot develops in about 20% of diabetic patients which can decrease their quality of life. This clinical trial study was conducted to evaluate the effect of Beneh ointment on the improvement of diabetic foot in out-patient and in-patient diabetic patients referred to Beheshti hospital. The inclusion criterion is strict evidence of diabetic (2 times: FBS >126 mg/dl) and clinical findings suggestive of infection of wound (erythematic, swelling, discharge). The patients are categorized in two groups. In one group only systemic antibiotic and in the second group the systemic antibiotic plus Beneh ointment are used. Clinical improvement of the wound and negative result of the wound culture are the main criterion for the effectiveness of Beneh ointment. The results of the study were analyzed by SPSS (version 14) using K square.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812243576N1**
Registration date: **2010-09-30, 1389/07/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-30, 1389/07/08

Registrant information

Name

Zahra Soleimani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0030

Email address

soleimani.zahra@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

kashan university of medical science

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-06-22, 1389/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Pistachio (mutica or atlantica) in improvement of diabetic foot

Public title

Evaluation of the effectiveness of Pistachio (mutica or atlantica) in improvement of diabetic foot

Purpose

Treatment

Inclusion/Exclusion criteria

Patients have with definitive diabetic and lower limb infective ulcer

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
kashan university of medical science

Street address
Kashan-ghotberavandi Boulevard

City
Kashan

Postal code
8715988141

Approval date
empty

Ethics committee reference number
4948/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Diabetic foot

ICD-10 code
E14.5

ICD-10 code description
With peripheral circulatory complication:diabetic ulcer

Primary outcomes

1

Description
depth of ulcer

Timepoint
7 days

Method of measurement
infectious disease specialist with a ruller

2

Description

tempreture at ulcer bed

Timepoint
7 days

Method of measurement
infectious disease specialist with termometer

3

Description
diameter of ulcer

Timepoint
7 days

Method of measurement
the wounds shape is transferred on to a checkered using a nylon

Secondary outcomes

1

Description
Number of days till recovery

Timepoint
7 days

Method of measurement
infectious specialist, counting the days after treatment started

2

Description
infection complication

Timepoint
7 days

Method of measurement
infectious specialist, culture of wound secretions

Intervention groups

1

Description
In interventional group, Beneh ointment and systemic antibiotic are used. Topical ointment is derived from Pistachio plant. It consist of 50% Pistachio, 30% lanoline, 20% ucerine. It applied as a tine layer on the surface of the wound (once daily, at least 1 week). Systemic antibiotic consist of: Cloxacillin Amp 1 g q6h, Ceftriaxone Amp 1 g q12h, Clindamycin Amp 600 mg q6h(at least: 7 days)

Category
Treatment - Drugs

2

Description
In control group used only systemic antibiotic: Cloxacillin Amp 1 g q6h, Ceftriaxone Amp 1 g q12h, Clindamycin Amp 600 mg q6h (at least: 7 days)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

infectious ward Beheshti hospital

Full name of responsible person

Dr. Zahra Soleimani

Street address

ghotbe ravandi boulevard-beheshti hospital-infectious disease ward

City

kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan university of medical sciences

Full name of responsible person

Vice chancellor for research

Street address

ghotbe ravandi boulevard

City

kashan

Grant name

7901000

Grant code / Reference number

8854

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

Yes

Title of funding source

Kashan university of medical sciences

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

kashan university of medical science

Full name of responsible person

Dr Zahra Soleimani

Position

infectious disease specialist

Other areas of specialty/work

Street address

kashan - boulevard ghotbeh ravandi -beheshti hospital-infectious disease ward

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Zahra Soleimani

Position

infectious disease specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Zahra Soleimani

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infectious disease specialist

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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