Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of healing effect of aqueous extract from one Artemisia spp on diabetic foot ulcer with classic treatment: a clinical trial.

Protocol summary

Summary

In a randomized clinical trial, healing effect of a herbal extract from Artemisia spp on diabetic foot ulcer is studied. Eighteen diabetic patient (type 1 or 2), between the age of 18-75 years, from either sex, who have Grade<3 Wagner classification diabetic foot ulcer, and with out "evidence of systemic or local infection such as purulent drainage and osteomyelitis;erythema in the edge of wound with 3 centimeter width and exposed bone at the wound site;sever and chronic ischemia of lower limb with out presence of pulsation;foot gangrene such that a surgical treatment is required", randomly allocated in test or control groups. The test group will receive topical Artemisia extract, while classic treatment including cleaning of the wounds, renewal of the dressing and antibiotic therapy is perform in the control group. Healing of the wounds is monitored carefully using direct observation by the physician and digital photography. The images will be sort based on date of photography and area of the wounds as well as their healing rate will be calculated using Auto-CAD soft ware.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105236565N1**
Registration date: **2011-07-06, 1390/04/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-06, 1390/04/15

Registrant information

Name

Gholam Reza Bahrami

Name of organization / entity

Kermanhsah University of Medical Science

Country

Iran (Islamic Republic of)

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+98 83 1428 1562

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, kermanshah University of Medical Sciences

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of healing effect of aqueous extract from one Artemisia spp on diabetic foot ulcer with classic treatment: a clinical trial.

Public title

Determination of the efficacy of artemisia extraction dressing on the healing of diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of diabetic foot ulcer in type 1 or 2 diabetes mellitus patient;age between 18 and 75 years with diabetic foot ulcer;The ulcer of the the patients have been caused by peripheral neuropathy; uncontrolled hyperglycemia;trauma; diabetic foot ulcers

which remained open without healing and/or improvement for at least 2 week;Patients should be available for 2 months and to be able to adhere to the treatment regime. Exclusion criteria:patients with ≥Grade III Wagner classification diabetic foot ulcers;evidence of systemic or local infection such as purulent drainage and osteomyelitis; erythema in the edge of wound with 3 centimeter width and exposed bone at the wound site; sever and chronic ischemia of lower limb without presence of pulsation;simultaneous diseases which had impact on healing process such as vasculitis or different types of cancers;hepatic or renal failure;endocrine;hematological or immunologic disorder;past history of/current acute or chronic autoimmune disease;chronic alcohol or drug abuse;immunosuppressive drugs;cytotoxic agents;radiation therapy and chemotherapy were excluded.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **18**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committe of Kermanshah University of Medical Sciences and Health Services

Street address
Beheshti blv, Kermanshah, Iran

City
Kermanshah

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
7/420/1900321

Health conditions studied

1

Description of health condition studied
Diabetic foot

ICD-10 code
E10, E11,

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Diameter reduction rate

Timepoint
Weekly for 2 months

Method of measurement
Evaluation of diameter with precise measurement with digital photo

Secondary outcomes

1

Description
Percentage of complete healing

Timepoint
Weekly for 8 week

Method of measurement
Evaluation of percentage of complete healing with precise measurement with Digital photo

Intervention groups

1

Description
The test group will receive topical Artemisia extraction, twice a day, and follow up weekly for 2months or until the complete healing of the wounds. Evaluation of diameter, percentage of healing and mean duration of healing calculated with digital photos and Auto CAD soft ware.

Category
Treatment - Drugs

2

Description
The control group will received classic treatments for diabetic foot ulcer, and follow up weekly for 2 months or until the complete healing the wound. Evaluation of diameter, percentage of healing and mean duration of healing calculated with digital photos and Auto CAD soft ware.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetic Research Center in Kermanshah
Full name of responsible person
Dr Mehr Ali Rahimi
Street address
Beheshti Blv, Kermanshah, Iran
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University Of Medical Sciences and Health Services
Full name of responsible person
Dr Farid Najafi
Street address
Kermanshah University Of Medical Sciences, Beheshti blv, kermanshah, iran
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Kermanshah
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, Kermanshah University Of Medical Sciences and Health Services
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
Kermanshah University of Medical Science
Full name of responsible person
Dr Gholam Reza Bahrami
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Person responsible for updating data

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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