

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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

Kermanshah University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1428 1562

##### Email address

gbahrami@kums.ac.ir

##### 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  $\geq$ 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 committee 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

**City**

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

**Position**

Professor

**Other areas of specialty/work**

**Street address**

pharmacy faculty, kermanshah, Iran.

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Science

**Full name of responsible person**

Dr Mehr Ali Rahimi

**Position**

Associate Professor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Science

**Full name of responsible person**

Saeedeh Malek Hosseini

**Position**

pharmacy student

**Other areas of specialty/work**

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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*