

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

effect of ultrasonic wound debridement in diabetic foot ulcers

Protocol summary

Summary

This study is a randomized clinical trial for comparison of evaluation diabetic foot ulcer debridement with the help of ultrasonic waves compared with sharp debridement with regard to rate of wound healing (complete epithelization without septic drainage) in 40 diabetic patients with chronic wounds (grade: Wegener 3). Patients have been referred to diabetes clinic of Shariati hospital in Tehran. Inclusion criteria: - patients with diabetic foot ulcers are classified according to Wagner with 3 grades (without necrotizing fasciitis or joint infection). - Patient's satisfaction and cooperation - ABI =. 5-1.2, Toe pressure > 50 mmHg. Exclusion criteria from the study: - diabetic foot patients that classification of ulcer based on Wagner is higher than 3 grade or with necrotizing fasciitis and joint infection. - Metal elements such as artificial joints, plate and screws and electronic devices are implanted in the wound. Ultrasonic wound debridement is done using device called Sonoca 180 manufacturing Soring Company in Germany. This device works with low-frequency ultrasonic waves around 24 Hz with three different props that has been designed according to the shape and type of wound and are connected to a serum containing 9% saline. Normal saline is sprayed on the surface of the wound with adjustable speed with simultaneous debridement and dissemination of Ultrasound waves. Because ultrasonic waves require moist environment and also cause necrotic and infected material to be cleaned out and props become cool. Number of debridements during the study can be determined based on both grade and speed wound healing. Study outcome measures: Evaluation of wound healing without damage to healthy tissue, pain during Debridement, bactericidal effect and relationship of these three factors with ischemic conditions and neuropathy and other risk factors of diabetic foot ulcers in two ways of debridement (Sharp - ultrasonic)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903271414N21**

Registration date: **2010-06-17, 1389/03/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-17, 1389/03/27

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

Endocrine & metabolic research institute-Tehran
university of medical science -Kavosh Pasand Novin
Company

Expected recruitment start date

2009-01-20, 1387/11/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
effect of ultrasonic wound debridement in diabetic foot ulcers

Public title
comparison between ultrasonic wound debridement and sharp debridement in diabetic foot ulcers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: -patients with known type 1 &2 diabetes - Diabetic patients with chronic and none healing foot ulcers that need continual debridement - diabetic patients with diabetic foot ulcer (3 Wagner's grade without necrosis fashiatis or contiguous joint infection) -patient's assistance - ABL=.5-1.2, TOE PRESSURE>50 mmHg Exclusion criteria: Diabetic patients with (Wagner's grade>3 with necrosis fashiatis or contiguous joint infection) -being metal devices in foot ulcer such as false joint, nail or metal plate, electrical tools

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Endocrine & metabolic research institute-Tehran university of medicak science

Street address
Shariati Hospital-North Kargar street-

City
Tehran

Postal code

1411413137

Approval date
empty

Ethics committee reference number
E-0055

Health conditions studied

1

Description of health condition studied
diabetic foot ulcer

ICD-10 code
Z86.31

ICD-10 code description
personal history of diabetic foot ulcer

Primary outcomes

1

Description
Rate of healing

Timepoint
1, 3, 6 months after beginning of debridement or Intervention

Method of measurement
wound area calculation

Secondary outcomes

1

Description
Bactericidal effect

Timepoint
Before and after first wound debridement and final wound debridement

Method of measurement
Colony count

2

Description
Pain Evaluation

Timepoint
after every wound debridement

Method of measurement
visual analogue scale

Intervention groups

1

Description
Intervention group Debridement is done with the help of ultrasonic waves and wet dressing with gas is carried out. Normally debridement is done once a week unless the situation is so wound that required debridement performed twice a week . The long-term study is at least 6 months and maximum until wound healing is complete.

Category

Treatment - Surgery

2**Description**

Control group is similar to intervention group and only differ in the type of debridement that is performed with surgical blade

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetic foot clinic located in diabetes and metabolic center-shariati Hospital

Full name of responsible person

Dr. Sareh Amini -researcher

Street address

Beside emergency door of heart center; North Kargar

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Endocrine & metabolic research institute-Tehran university of medicak science

Full name of responsible person

Dr.Bagher Larijani Presidency of Endocrine & metabolic research institute

Street address

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

Endocrine & metabolic research institute-Tehran university of medicak science

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**

Kavosh Pasand Novin Company

Full name of responsible person

Meisam Alikhani

Street address

No 6, Oraman Street, South Sohrevardi

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kavosh Pasand Novin 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**

Endocrine & metabolic research institute

Full name of responsible person

Dr. Mohamadreza Mohajrri

Position

Endocrinologist-assistant of endocrine research center

Other areas of specialty/work**Street address**

Shariati Hospital, North Kargar st.,

City

Tehran

Postal code

1411413137

Phone

00982188220037; 00982188220038

Fax

+98 21 8822 0052

Email

emrc@tums.ac.ir

Web page address

emrc.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Endocrine & metabolic research institute

Full name of responsible person

Dr. Sareh Amini - researcher

Position

General Physician-researcher

Other areas of specialty/work**Street address**

Shariati Hospital, North Kargar st.,

City

Tehran

Postal code

1411413137

Phone

00982188220037; 00982188220038

Fax

+98 21 8822 0052

Email

emrc@tums.ac.ir

Web page address

emrc.tums.ac.ir

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