Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 fasciatis 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 fascitis 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 , bacticidal 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 medicak 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 - ABI=.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