Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison excision and grafting (early and delayed) versus conventional methods in the management of diabetic foot ulcers

Protocol summary

Summary

The purpose of this study was to investigate the effectiveness using excision and grafting (early and delayed) for the treatment of diabetic foot ulcer and comparing it with conventional methods. This non-randomized clinical trial was performed on 50 patients with a history of type 1 or type 2 diabetes presenting for care of a diabetic ulcer of the foot at three teaching hospitals of Shiraz University of Medical Sciences (Ghotboddin, Namazi, and Shahid faghihi) during 6 months period from November 2014 to April 2015. Study inclusion criteria were as follows: age at least 18 years or older; ulcer size>1 and <25 cm2; no clinical signs of systemic infection; adequate circulation to the affected extremity. Patients with index ulcer probing to bone, connective tissue disorders, immune suppressive disorders, severe protein malnutrition, and use of medication that would affect epithelialization were excluded from this study. The patients were divided into two groups. Individuals who referred to Ghotboddin hospital were treated by early and delayed excision and grafting method. On the other group, individuals who referred to Namazi and Shahid Faghihi hospitals were treated by conventional methods. The primary outcome measure was healing status on discharge based on surgeon's viewpoint. In addition, we considered the number of foot amputation and length of hospital stay as secondary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017103013880N5**
Registration date: **2017-11-04, 1396/08/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-04, 1396/08/13

Registrant information

Name
Mehdi Ayaz
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-10-21, 1395/07/30

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison excision and grafting (early and delayed) versus conventional methods in the management of diabetic foot ulcers

Public title

Excision and grafting (early and delayed) for treatment of diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age at least 18 years or older; Ulcer size>1 and <25 cm 2; No clinical signs of systemic infection; Adequate circulation to the affected extremity. Exclusion criteria: Patients with index ulcer probing to bone; Connective tissue disorders; Immune suppressive disorders; Severe protein malnutrition; Use of medication that would affect epithelialization

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not 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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters of Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Postal code

Approval date

2016-10-04, 1395/07/13

Ethics committee reference number

IR.SUMS.MED.REC.1395.07

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

L97

ICD-10 code description

Ulcer of lower limb

Primary outcomes

1

Description

Healing status

Timepoint

On discharge

Method of measurement

Surgeon’s viewpoint

Secondary outcomes

1

Description

Number of foot amputation

Timepoint

On discharge

Method of measurement

Observation

2

Description

Length of hospital stay

Timepoint

On discharge

Method of measurement

Observation

Intervention groups

1

Description

Individuals who referred to Ghotboddin hospital were treated by early and delayed excision and grafting method

Category

Treatment - Surgery

2

Description

Individuals who referred to Namazi and Shahid Faghihi hospitals were treated by conventional methods

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghotbodin Center for Burn Managemenet and

Treatment

Full name of responsible person
Mehdi Ayaz

Street address

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Burn Research Center of Shiraz University of Medical Sciences

Full name of responsible person
Mitra Zardasht

Street address
Ghotbodin Hospital

City
Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
Burn Research Center of Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Mehdi Ayaz

Position
Assistant Professor of Surgery of Shiraz University of Medical Sciences

Other areas of specialty/work

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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