

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 71 1235 2559

Email address

ayazm@sums.ac.ir

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 Management 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
Street address
Ghotbodin Hospital
City
Shiraz
Postal code
Phone
+98 71 3235 9317
Fax
Email
ayazm@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Ayaz
Position
Assisntent Professor of Surgery in Shiraz University of Medical Sciences
Other areas of specialty/work
Street address
Ghotbodin Hospital
City
Shiraz
Postal code
Phone
+98 71 3235 2559
Fax
Email
ayazm@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Ayaz
Position
Assisntent Professor of Surgery in Shiraz University of Medical Sciences
Other areas of specialty/work
Street address
Ghotbodin Hospital
City
Shiraz
Postal code
Phone
+98 71 3235 2559
Fax
Email
ayazm@sums.ac.ir
Web page address

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