Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of Efficacy of Tebaderm Wound Dressing vs. Moist Wound Dressing in the Treatment of Diabetic Wounds in a Randomized Clinical Trial

Protocol summary

Study aim
Evaluation of TEBADERM Dressing in Comparison with Standard Moist Dressing in Treatment of Chronic Diabetic foot Ulcer

Design
In this study, 60 patients with Wagner Grade 2 diabetic foot ulcer will be recruited in two groups. This study will be a randomized clinical trial that the patients after standard treatment (debridement, infection control and off-loading) will be allocated in both intervention group (a chitosan based dressing- TEBADERM) and standard moist dressing for wound care. the patients will been followed weekly up to first months, biweekly up to third months and monthly up to six months. The outcomes will be wound area changes, complete healing, parenteral antibiotic therapy and hospitalization

Settings and conduct
This study will be conducted at Wound Healing Center of ACECR as a Phase 3 open labeled randomized clinical trial.

Participants/Inclusion and exclusion criteria
Chronic neuropathic diabetic foot ulcer (more than 6 weeks) with wound classification Wagner I & II full informed consent for recruitment in random allocation

Intervention groups
Intervention group is the using TEBADERM hydrogel dressing and control group is the using standard moist wound dressing.

Main outcome variables
complete healing rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170612034485N1**
Registration date: **2018-01-03, 1396/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-03, 1396/10/13**
Update count: **0**

Registration date
2018-01-03, 1396/10/13

Registrant information

Name
Gholamreza Esmaeeli Djavid

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6698 9110

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Recruitment status
Recruitment complete

Funding source
Medical Laser Research Center, Academic Center for Education, Culture and Research Tebazist Polymer Company

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-03-20, 1396/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Efficacy of Tebaderm Wound Dressing vs.

Moist Wound Dressing in the Treatment of Diabetic Wounds in a Randomized Clinical Trial

Public title
Evaluation of Hydrogel dressing in treatment of Diabetic foot Ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1) Chronic neuropathic diabetic foot ulcer (more than 6 weeks) with wound classification Wagner I & II full informed consent for recruitment in random allocation
Exclusion criteria:
Suspected osteomyelitis Evidence of severe Ischemia (ABI less than 0.8) ESR more than 70 Using corticosteroid or immuno-suppressor drug Chronic renal failure of Hemodialysis Charco Joint Suspected malignancy
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation of patients will bee done based on block randomization.
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
Motamed Cancer Institute (MCI)
Street address
146, South Gandi Ave, Vanak Sq, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1517964311
Approval date
2017-10-08, 1396/07/16
Ethics committee reference number
IR.ACECR.IBCRC.REC.1396.12

Health conditions studied

1

Description of health condition studied
Chronic diabetic foot Ulcer
ICD-10 code
E11.621
ICD-10 code description
Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description
complete wound healing during study (at least 6 months)
Timepoint
every month up to Month 6th
Method of measurement
inspection

2

Description
changes of wound area
Timepoint
week 1, 2, 3, 4, 6 month 3, 4, 6
Method of measurement
photography

Secondary outcomes

1

Description
IV Antibiotic therapy
Timepoint
every month up to month 6th
Method of measurement
clinical examination

Intervention groups

1

Description
Intervention group: in this group, the patients will use TEBADERM dressing on their granulated wound daily. the dressing will be changed every 24 hours.
Category
Treatment - Devices

2

Description
Control group: in this group, the patients will use

standard dressing which it moisturizes with normal saline every 6 hours.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Wound Healing Center, ACECR of Tehran Unversity of Medical Sciences Branch

Full name of responsible person
Gholamreza Esmaeeli Djavid

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No. 66 Abourihan Street

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Web page address
http://jdtums.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Seyed Mehdi Tabaie

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tebazist Polymer

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

2

Sponsor

Name of organization / entity
Tebazist Polymer

Full name of responsible person
Mahmood Ghafghazi

Street address
No. 7, Balavar Alley, Valiaser

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Grant name

Grant code / Reference number

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

Title of funding source
Tebazist Polymer

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and

research

Full name of responsible person
Gholamreza Esmaeeli Djavid

Position
MD-PhD/ Director

Latest degree
Ph.D.

Other areas of specialty/work
Biophysics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Gholamreza Esmaeeli Djavid

Position
PhD-MD

Latest degree
Ph.D.

Other areas of specialty/work
Biophysics

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Person responsible for updating data

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Zahra Torabi Nasaj

Position
Adiminstration

Latest degree
Bachelor

Other areas of specialty/work
Medical Informatics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All NA data will be accessible after publication.

When the data will become available and for how long
Time duration for access to the data will begin after publication for 2 years.

To whom data/document is available
Academic faculty member

Under which criteria data/document could be used
Systematic review and meta-analysis

From where data/document is obtainable
Contact with scientific correspondence of the project

What processes are involved for a request to access data/document
via written request letter

Comments