

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 be 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 Djauid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6698 9110

Email address

djauid@ut.ac.ir

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

2017-10-08, 1396/07/16

Ethics committee reference number
IR.ACECR.IBCRC.REC.1396.12

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 be 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 Gandhi Ave, Vanak Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1517964311

Approval date

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 University of Medical Sciences Branch

Full name of responsible person

Gholamreza Esmaeeli Djavid

Street address

No. 66 Abourihan Street

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Web page address

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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

Iranian academic center for education culture and research

Full name of responsible person

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Position

PhD-MD

Latest degree

Ph.D.

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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