

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of Safety and Efficacy of Hydropolymer Dressing (Hydrogel) with Thymol for the Treatment of Neuropathic Diabetic Foot Ulcer in a Phase I/II Clinical Trial

Protocol summary

Study aim

Evaluation of Safety and Efficacy of Hydropolymer Dressing (Hydrogel) with Thymol for the Treatment of Neuropathic Diabetic Foot Ulcer

Design

In this study, 20 volunteers with Wagner Grade 2 diabetic foot ulcer will be recruited. This study will be a phase I and II clinical trial that the patients after standard treatment (debridement, infection control and off-loading) will be used thymol-honey (Herbaderm) for wound care. The investigators will follow the patients for weekly up to first months, biweekly up to third months and monthly up to six months. The outcomes will be local and systemic reactions, wound area changes, and frequency of complete healing during study period.

Settings and conduct

This study will be conducted at Wound Healing Center of Yara Institute, ACECR, as a Phase I and II clinical trial in the volunteers with neuropathic diabetic foot wound.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic neuropathic diabetic foot ulcer (more than 6 weeks) with wound classification Wagner II full informed consent for recruitment in the study Suitable tissue perfusion ($ABI > 0.8$) and normal flow of main arteries in lower extremities Exclusion criteria: Suspected osteomyelitis Using corticosteroid or immunosuppressor drug Chronic renal failure or hemodialysis

Intervention groups

Thymol-honey gel dressing (Herbaderm) and control group is the using standard moist wound dressing

Main outcome variables

1) Local and systemic side effects 2) complete healing rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170612034485N3**

Registration date: **2018-12-30, 1397/10/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-30, 1397/10/09**

Update count: **0**

Registration date

2018-12-30, 1397/10/09

Registrant information

Name

Gholamreza Esmaeeli Djavid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6698 9110

Email address

djavid@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Safety and Efficacy of Hydropolymer Dressing (Hydrogel) with Thymol for the Treatment of Neuropathic Diabetic Foot Ulcer in a Phase I/II Clinical Trial

Public title

Thymol Dressing in Diabetic foot Ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic neuropathic diabetic foot ulcer (more than 6 weeks) with wound classification Wagner I & II Full informed consent for recruitment in the study Age between 18-70 years

Exclusion criteria:

Suspected osteomyelitis Using corticosteroid or immunosuppressor drug Chronic renal failure and hemodialysis

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Motamed Cancer Institute (MCI)

Street address

ACECR Central Office, No. 1270 Enqelab Avenue

City

Tehran

Province

Tehran

Postal code

1517964311

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.ACECR.IBCRC.REC.1397.004

Health conditions studied**1****Description of health condition studied**

Chronic neuropathic diabetic foot Ulcer

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

Primary outcomes**1****Description**

Local and systemic side-effects

Timepoint

Every month up to month 6th (or complete healing)

Method of measurement

Clinical examination

2**Description**

Complete wound healing during study (at least 6 months)

Timepoint

Every month up to month 6th

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: in this group, the patients will use thymol-honey (Herbaderm) dressing on their granulated wound daily. the dressing will be changed every 24 hours.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Wound Healing Center, Yara Institute, ACECR

Full name of responsible person

Gholamreza Esmaeeli Djavid

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No. 65 Abourihan Street

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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?

Yes

Title of funding source

Iranian academic center for education culture and research

Proportion provided by this source

20

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

Atin Biopolymer Products (Joint Stock)

Full name of responsible person

Alireza Kamangar

Street address

Unit4, No. 8, Corner of the 6th West Alley, Farhang Square, 24 Meter Boulevard, Saadat Abad

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Email

ar.kamangar@gmail.com

Web page address

<https://atinmed.com/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Atin Biopolymer Products (Joint Stock)

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

Assistant Professor, MD-PhD

Latest degree

Ph.D.

Other areas of specialty/work

Biophysics

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Person responsible for scientific inquiries

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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

Not applicable

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

Not applicable

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