Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Study aim

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

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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Web page address
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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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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
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Other areas of specialty/work
Biophysics
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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