Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Preparation, evaluation, and comparison of two topical semisolid formulations containing insulin for improvement and acceleration of diabetic wound.

Protocol summary

Study aim
Topical Insulin efficacy

Design
In this research, 20eligible patients referring to diabetic wounds were chosen and assigned to the intervention group.

Settings and conduct
This study is done in the skin and leprosy center.20 patients are selected for the study. Patient tracking is done up to 12 weeks after treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diabetic ulcer with at least1cm2 with gradeIIWagner calcification -Over 5ABI-Over3MDNS
Exclusion criteria: Dermatitis-Patients who received other treatments for their diabetic ulcers like antibiotic therapy- Infectious diabetic wounds.

Intervention groups
According to the entry and exit criteria,20patients are selected for the study. Each patient receives training for wound care and training related to washing and wound dressing at intervals to visit the center. Patient tracking is done up to 12 weeks after treatment or complete recovery. Instructions for wound care in the study: After wearing sterile gloves and washing the powder with sterile water, the wound should only be washed with normal saline or sterile water. If you see necrotic tissue, perform a gentle cleansing with saline-soaked gas. Wash exposed to open air for 15-15 minutes. Avoid wound drying. A half centimeter thick layer of gel is placed on the wound, without contact with the hand or any other means. Then add a multi-layer sterile gauze on the wound and apply with 3M anti-allergenic adhesive. Patient education: Wound washing and wound dressing. Exercise lower limb movement while sitting and lying. Use underarm cane to prevent pressure on the wound. The need for a weekly visit to a research center to receive regular medication and track the recovery rate and weekly imaging.

Main outcome variables
Accelerating the repair of ischemic, necrotic, gangrene, osteomyelitis, pressure ulcers, fistulas, surgical and skin grafts.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170903036045N2**
Registration date: **2020-04-17, 1399/01/29**
Registration timing: **retrospective**

Last update: **2020-04-17, 1399/01/29**
Update count: **0**

Registration date
2020-04-17, 1399/01/29

Registrant information

Name
Farid Dorkoosh

Name of organization / entity
Tehran university of medical sciences

Country
Iran (Islamic Republic of)

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+98 21 8800 9440

Email address
dorkoosh@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-10, 1398/12/20

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preparation, evaluation, and comparison of two topical semisolid formulations containing insulin for improvement and acceleration of diabetic wound.

Public title
Preparation, evaluation and comparison of two topical semisolid formulations containing insulin for improvement and acceleration of diabetic wound.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 Diabetic ulcer with at least 1 cm2 with grade II Wagner calcification Over 5 ABI Over 3 MDNS Willingness to participate in the study

Exclusion criteria:
Nursing and pregnant woman Immunosuppressive therapy Immunosuppressive disorder Kidney disorder (Cr>2.5) CHF, CABG, Cardiomyopathy HA1C>10 Smoking Alcohol and drugs Dermatitis Patients who received other treatments for their diabetic ulcers like antibiotic therapy Infectious diabetic wounds

Age
From **18 years** old

Gender
Both

Phase
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
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran university of medical sciences

Street address
Floor 13th, block A, Headquarter of the ministery of health and medical education, Simaye Iran St, Qods town

City
tehran

Province
Tehran

Postal code
1467664961

Approval date
2020-02-11, 1398/11/22

Ethics committee reference number
IR.TUMS.VCR.REC.1398.917

Health conditions studied

1

Description of health condition studied
Diabetic wounds

ICD-10 code
s81

ICD-10 code description
Open wound of knee and lower leg

Primary outcomes

1

Description
Wound surface

Timepoint
Every weeks up to 12 weeks

Method of measurement
Ealipers

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1) Wound should be washed with sterile NS or sterile water after wearing sterile gloves. 2) If there is any necrosis, debridement should be done gently by sterile gauze pads (wet with sterile NS). 3) After washing, wounds should be allowed to dry in room atmosphere 4) Wound should not be dried by using any gauze or other means 5) A 0.5 mm thick layer of insulin gel (100 IU per mL of insulin) should be applied on the surface of the wound without any contact with the hand or another applicator 6) A suitable piece of sterile Gauze layers should be placed on the surface of the wound and be dressed by anti-allergic 3M tape.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Center for research and training of skin diseas and leprosy

Full name of responsible person
Dr. Alireza firoz

Street address
No. 415, Shahid naderi street, Taleghani Ave

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Tehran

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Tehran

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1416613675

Phone
+98 21 8897 2221

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firozali@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Esmaeel Haririan

Street address
Enghelab Sq, Tehran, Iran

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1417614411

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mbrc@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

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

Person responsible for general inquiries

Contact

Name of organization / entity
Skin and leprosy center

Full name of responsible person
Dr.mohamad ali palar

Position
Consultant

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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No. 415, Shahid Naderi street, Taleghani Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Skin and leprosy center

Full name of responsible person
Dr.alireza firooz

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Skin specialist

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Center for research and training in skin disease and leprosy

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Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr.soheil haddadzadegan
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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No23, second avenue, gisha, keyhanpharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
These files will be available after completion of the study: Study protocol Consent form Report.
When the data will become available and for how long
Data will be available 6 months after completion of the study.
To whom data/document is available
Researchers of academic institutions and industry.
Under which criteria data/document could be used
Just for review of the study.
From where data/document is obtainable
Dr. Alireza Firoz Email: firozali@sina.tums.ac.ir Center for research and training of skin and leprosy.
What processes are involved for a request to access data/document
In order to request information regarding this clinical trial, send an email to the mentioned address containing the following information: Name and family name, education and field of work/study, the reason for requesting the information Based on the requested data, your request will be replied as soon as possible.
Comments