Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Clinical evaluation of therapeutic effects of emulsion bio-complex on non ischemic diabetic foot ulcers

Protocol summary

Study aim
Clinical evaluation of therapeutic effects of bio-complex on non ischemic diabetic foot ulcers

Design
In this study, 60 patients who referred for surgery were divided into two groups of control and intervention and four randomized blocks were used for randomization. A double-blind study will be.

Settings and conduct
This study , which is carried out at the Sina Hospital. Medical ethics and Consent is under supervision of the Medical Ethics Committee of the Tehran University of Medical Sciences. The study is a randomized, double blind, clinical trial with two intervention and control groups. Patients are randomly divided into two groups of 30. Randomly, 30 people will be in the intervention group and 30 will be in the control group. The control group treatment is Vaseline. In this study, the Patients, Researcher and Therapist are blinded. Ointments will be given in the unbranded and untitled medical cans that patient and therapist be blind.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1- Is Come for Surgery 2- The Lesion Not be Malignant 3- No Specific or Immunosuppressive Disorders 4- Not be Pregnant or in Lactation 5- Not Use Any Specific Drug . Exclusion Criteria: 1- The Ability to Create Colloid or Scar from the Injuries 2- The presence of Underlying Disease 3- Previous or Current History of Scleroderma 4- Previous Radiotherapy 5- Use Immunosuppressive Medicine or Have Immunodeficiency Disorders 6- Pregnancy or Lactation 7- Use Specific Drug 8- Dissatisfaction to continue use ointment

Intervention groups
The intervention group in this study is a randomly selected 30-person group that uses an alternative medicine to improve the wound healing process. The control group is a randomly selected 30-person group that uses conventional treatment Vaseline.

Main outcome variables
Less pain; Heal faster

General information

Reason for update

Acronym
Minhal

IRCT registration information
IRCT registration number: **IRCT20160118026096N2**
Registration date: **2020-12-14, 1399/09/24**
Registration timing: **prospective**

Last update: **2020-12-14, 1399/09/24**
Update count: **0**

Registration date
2020-12-14, 1399/09/24

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2234 0598

Email address
takzaree@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-04-21, 1400/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Clinical evaluation of therapeutic effects of emulsion bio-complex on non ischemic diabetic foot ulcers

Public title
The effect of emulsion on the Process of diabetic wound healing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Is Come for Surgery .The Lesion Not be Malignant No Specific or Immunosuppressive Disorders Not be Pregnant or in Lactation Not Use Any Specific Drug .

Exclusion criteria:
The Ability to Create Colloid or Scar from the Injuries The presence of Underlying Disease Previous or Current History of Scleroderma Previous Radiotherapy Use Immunosuppressive Medicine or Have Immunodeficiency Disorders Pregnancy or Lactation Use Specific Drug Dissatisfaction to continue use ointment

Age
From **25 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the permuted block randomization will be used with quadruple blocks. Blocks will be generated using Excel software. In order to apply concealment in the randomization process, sealed envelopes will be used, and therefore, before choosing a person, one will not be aware of the type of treatment he will receive.

Blinding (investigator's opinion)
Double blinded

Blinding description
Ointments will be given in the unbranded and untitled medical cans that patient and therapist be blind.

Placebo
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
Room 60., Sixth Floor., Tehran University of Medical Sciences., Qods St., Tehran

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2020-11-14, 1399/08/24

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.741

Health conditions studied

1

Description of health condition studied
Diabetic Wound Healing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Wound Surface

Timepoint
Day one (surgery day), Day 1 , 15 and 45 after surgery

Method of measurement
Wound healing is evaluated by measuring the wound surface, the percentage of wound healing, and the length of time needed for closure and complete repair of the wound. The surface of the wound is measured on days 1, 4, 7 and 14 after the surgery with Ferguson and Logan method.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group in this study is a randomly selected 30-person group that uses an alternative medicine to improve the wound healing process. The control group is a randomly selected 30-person group that uses conventional treatment Vaseline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital
Full name of responsible person
Nasrin Takzaree
Street address
Hasanabad Sq., District 12., Tehran., Tehran Province
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sinahospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

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Tehran University of Medical Sciences
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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
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
Tehran University of Medical Sciences
Full name of responsible person
Nasrin Takzaree
Position
Assistant professor,School of Medicine, Tehran University of Medical Sciences
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Person responsible for updating data

Contact

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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
No - There is not a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Patient recovery results

When the data will become available and for how long
En 6 months after printing

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Only recovery results are reported

From where data/document is obtainable
takzaree@tums.ac.ir

What processes are involved for a request to access data/document
Particular information will not be sent.

Comments