

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

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Hasanabad Sq., District 12., Tehran., Tehran Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tehran University of Medical Sciences

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Tehran University of Medical Sciences, Qods Ave.

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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

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

Name of organization / entity

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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