Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical Evaluation of Topical Nanocomplex ointment on Chronic venous ulcers: A double-blind randomized clinical trial

Protocol summary

Study aim

Clinical evaluation of the topical effect of nanocomplex ointment on the healing process of chronic venous wounds

Design

A randomized, double-blind clinical trial in both intervention and control groups

Settings and conduct

1-Provide explanation to the patient 2-Signing the consent form 3-Examine and assess 4-active wounds. 5-Surgery by a general surgeon (the Vascular Surgery Clinic of Sina Hospital) control Wounds are washed with normal saline.Vaseline compression dressing intervention wounds are washed with normal saline and coverd with Promenton ointment and bandaged. (once a day until the 14th day). Each time an ointment is applied to the wound, it is applied to the wound surface. (days 1, 7 and 14).

Participants/Inclusion and exclusion criteria

Inclusion C. 1-Age range 30 to 60 years 2- treatment of chronic venous ulcers. 3-The lesion is clinically benign. Exclusion C. 1- clinically malignant. 2-The ability to create keloids or scars 3.Previous or current history of scroderma 4.History of radiotherapy 5.Immunosuppressive use or defective immune system 6.Pregnancy or breastfeeding 7.Patient dissatisfaction with continued use of ointment

Intervention groups

This clinical trial study was performed on 60 patients referred to the Vascular Surgery Clinic of Sina Hospital who complained of venous leg ulcers. control :After surgery and cessation of bleeding in the control group, patients' wounds are washed with normal saline .Vaseline compression dressing is then applied to the wound. intervention : After surgery and cessation of bleeding , patients' wounds are washed with normal saline .The patient's wound is covered with Promenton ointment and bandaged.Ointments are used once a day until the 14th day. Each time an ointment is applied to the wound, it is applied to the wound surface.Patients are visited on days 1, 7 and 14.

Main outcome variables

Wound surface measurement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160118026096N3**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **retrospective**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date

2021-08-22, 1400/05/31

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

2021-03-10, 1399/12/20

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Evaluation of Topical Nanocomplex ointment on Chronic venous ulcers: A double-blind randomized clinical trial

Public title

The effect of Topical Ointment on the Process of Wound Healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 30 to 60 years Have referred for the treatment of chronic venous ulcers. The lesion is clinically benign.6.

Exclusion criteria:

The lesion is clinically malignant. The ability to create keloids or scars due to injuries Previous or current history of scroderma History of radiotherapy treatment Immunosuppressive use or defective immune system Pregnancy or breastfeeding Patient dissatisfaction with continued use of ointment

Age

From **30 years** old to **60 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

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

2021-03-09, 1399/12/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1254

2

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

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Province

Tehran

Postal code

1417613151

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1254

Health conditions studied

1

Description of health condition studied

Wound Healing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

En Wound Surface

Timepoint

Day one (surgery day), Day 4, 7 and 14 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. This is accomplished by placing the transparent paper on the wound and draw the wound shape. Then the transparent paper is transferred to the millimeter lattice paper and counted.

Secondary outcomes

1

Description
Wound resizing
Timepoint
The wound surface is digitally photographed on days 1, 7 and 14 after surgery.
Method of measurement
The wound surface is digitally photographed on days 1, 7 and 14 after surgery.The wound surface is then measured with Image J software.

2

Description
Inflammation rate
Timepoint
On days 1, 7 and 14, the amount of inflammation is determined by the doctor.
Method of measurement
Determination of inflammation by a doctor 0-3 score(none- mild- moderate- severe)

3

Description
Determining the amount of pain
Timepoint
On days 1, 7 and 14, the patient is asked about the amount of pain by the doctor.
Method of measurement
Based on patient questions and classification 0-10 score *(no pain 0 / mild pain 1-3/ moderate pain 4-6 / severe pain 7-9 / worst pain 10)

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. Surgery by a general surgeon After cessation of bleeding in the control group, patients' wounds are washed with normal saline solution. Apply some ointment on the wound and bandage it .(10 mg - Nanocomplex ointment - Dineh Company)Ointments are used once a day until the 14th day
Category
Treatment - Drugs

2

Description
Control group: The control group is a randomly selected 30-person group that uses conventional treatment Vaseline. In the intervention group, after rinsing with normal saline, the patient's wound is covered with ointment and bandaged.(10 mg - Vaseline - Kimidaro Company)Ointments are used once a day until the 14th day .
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

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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
Undecided - It is not yet known if there will be 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

En Academic researchers

Under which criteria data/document could be used

Only recovery results are reported

From where data/document is obtainable

Dr. Nasrin Takzaree

What processes are involved for a request to access data/document

takzaree@tums.ac.ir

Comments