

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Clinical Evaluation of Topical Skin Ointment on the Process of Wound Healing Ointment: A Double-Blind Randomized Clinical Trial

Protocol summary

Study aim

Clinical evaluation of the effect of Topical Skin Ointment on the Process of Open Cutaneous Wound Healing

Design

In this study, 56 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 is based on the process of wound healing, which is carried out at the Razi Dermatology Hospital. The patients in the study, were referred to plastic surgery room for skin graft on their scar and burn site, and patients with a 3 × 3 cm skin removal are included in the study. 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. After receiving Informed Consent from patients, 56 patients will be selected. Patients are randomly divided into two groups of 28. Randomly, 28 people will be in the intervention group and 28 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 6- With Manual or Electric Dermatome a Layer Thickness in 0.04 mm And 3*3 cm in Size from the Thigh Will Removed. 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 28-person group that uses an alternative medicine to improve the wound healing process. The control group is a randomly selected 28-person group that uses conventional treatment Vaseline.

Main outcome variables

Less pain; Heal faster

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160118026096N1**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **prospective**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

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

2018-02-20, 1396/12/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Evaluation of Topical Skin Ointment on the Process of Wound Healing Ointment: A Double-Blind Randomized Clinical Trial

Public title

The effect of Topical Skin Ointment on the Process of 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 With Manual or Electric Dermatome a Layer Thickness in 0.04 mm And 3*3 cm in Size from the Thigh Will Removed.

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 **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **56**

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

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

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

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2017-11-05, 1396/08/14

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2641

Health conditions studied**1****Description of health condition studied**

Wound Healing

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

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

empty

Intervention groups

1

Description

The intervention group in this study is a randomly selected 28-person group that uses an alternative medicine to improve the wound healing process. The control group is a randomly selected 28-person group that uses conventional treatment Vaseline.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Dermatology Hospital

Full name of responsible person

Nasrin Takzaree

Street address

Vahdat-e-Islami St., District 12., Tehran., Tehran Province

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Email

razihospital@sina.tums.ac.ir

Web page address

<http://razihos.tums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Histology

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Patient recovery results

When the data will become available and for how long

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