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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razihospital@sina.tums.ac.ir
Web page address
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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
Latest degree
Ph.D.
Other areas of specialty/work
Histology
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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
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