

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Determination and Comparision the Effectiveness of Nano Propolis in Wound healing of the donor site Skin Graft in Patients

Protocol summary

Study aim

Efficacy of the Nanosized Composition of Propolis in Repairing the Donor Graft Site

Design

The clinical Trial has a Control Group and parallel Groups. Double-blind. Randomized. On 30 Patients. Based on the Block of Four Numbers prepared by Excel Software.

Settings and conduct

Patients in the plastic surgery, enter the study. In order to blind the patient and not know which cream was used in which area, the blinding will be done in a (double-blind) way, so that the patient will be given two gels in the same tubes. It is given and asked from the patient that it is the supervisor who knows which lesion of the patient with which code, which gel will be prescribed with which code, and the researcher and the patient do not know about the codes related to the lesions and the content of the gels.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with split-thickness graft candidate Exit criteria: • History of collection from Donor place • History of keloid and hypertrophic scar • smoking • history of hypersensitivity reaction to honey and its derivatives • Those who do not want to participate in the study history of impaired wound healing or diseases that interfere with the wound healing process • Elderly people (over 60 years old)/ Immunodeficiency • Pregnant

Intervention groups

The skin graft harvesting site is disinfected with 10% betadine and from two adjacent areas (one centimeter apart) with the same dimensions as the transplanted tissue. All skin grafts with a thickness of 0.4 mm from the antero-lateral area of the thigh.

Main outcome variables

wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220908055916N1**

Registration date: **2023-01-19, 1401/10/29**

Registration timing: **prospective**

Last update: **2023-01-19, 1401/10/29**

Update count: **0**

Registration date

2023-01-19, 1401/10/29

Registrant information

Name

Hamed Shahdadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119

Email address

hamedshahdadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination and Comparision the Effectiveness of Nano Propolis in Wound healing of the donor site Skin Graft in Patients

Public title

Effect of Nano Propolis in Donor Site Graft Healing

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients Scheduled for partial Thickness Skin Graft with informed Consent

Exclusion criteria:

history of graft harvest from donor site history of keloid and HTS Cigarette smoking allergy history to honey history of wound healing impairment disorder old age patient(>60 years old) immune deficient patient pregnant patient with out informed consent

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patients who meet the necessary conditions to enter the study, undergo surgery after complete anesthesia. The skin graft harvesting site is disinfected with 10% betadine solution and from two adjacent areas (one centimeter apart) with the same dimensions as the transplanted tissue. All skin grafts with a thickness of 0.4 mm from the antero-lateral area of the thigh are prepared by an electric dermatome. The areas that are selected as donors are randomly placed in one of the following two groups to receive panmesan with nano propolis medicinal composition and traditional treatment method.

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is not done to select People because the Case and Control are done on One Person, but Randomization is done for the Type of Cream in the Wound Healing Site. The Lesions on the Patient's Body will be randomly selected based on the Block Classification of Four Numbers prepared by Excel Software, and will be placed in One of the Two relevant Groups to receive the Panemsan Type

Blinding (investigator's opinion)

Double blinded

Blinding description

In Order to blind the Patient and not know which Cream was used in which Area, the Blinding will be done in a (double-blind) way, so that the Patient will be given Two Gels in the same Tubes. It is given and asked from the

Patient that It is the Supervisor Who knows which Lesion of the Patient with which Code, which Gel will be prescribed with which Code, and the Researcher and the Patient do not know about the Codes related to the Lesions and the Content of the Gels. Randomly, in One of the Two Skin Graft harvesting Sites, Treatment with Nano Propolis gel (Group A) and Placebo Treatment (base Gel without Propolis - Group B) will be used in the Other Place. Nanopropolis Gel and Placebo Gel are similar in Appearance, Weight, Color and Consistency and can only be recognized by a Special Code that was prepared by the pharmaceutical Company in cooperation with Sharif University and with the Formulation that is available in the Attachment, and the Researcher and the Patient They do not know about the Codes related to the Content of the Gels. The Random Selection Sequence of Groups A and B will be calculated by a Statistician and Methodology Expert and maintained by a Person Who has no Other Interest or Participation in the Project. The Researchers and Subjects and the Statistical Analyst will be blind to the Content of the Gels throughout the Study and during the statistical Analysis.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Imam Khomeini Hospital Tehran University of Medical Sciences

Street address

tehran, keshavarz blvd, imam khumeini hospital

City

تهران

Province

Tehran

Postal code

1444863841

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

ir.tums.ikhc.rec.1401.245

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

patients need skin graft

ICD-10 code

t14.0

ICD-10 code description

Superficial injury of unspecified body region

Primary outcomes

1

Description

wound healing according to bates-jensen criteria

Timepoint

1-3-7-14-21-28 day

Method of measurement

bates-jensen scoring

Secondary outcomes

1

Description

wound infection rate

Timepoint

1-3-7-14-21-28 day

Method of measurement

examination or culture

2

Description

pain

Timepoint

1-3-7-14-21-28 day

Method of measurement

visual analogue score

3

Description

scar

Timepoint

1-3-7-14-21-28 day

Method of measurement

physical exam

Intervention groups

1

Description

patients with skin defects candidated healing with partial thicknes skin grafts after harvesting the grafted skin at the donor site, which are divided into two equal parts with a distance, and each of these parts are selected as intervention and control subjects: intervention group: in the part that is randomly assigned to The place of intervention is selected, honey nano propolis ointment is prescribed, and after training, daily dressing is done, and on days 1-3-7-14-21-28, the condition of wound healing is checked using Bates-Jensen criteria.

Category

Treatment - Drugs

2

Description

Control group: Control group: Vaseline ointment is prescribed in the part that is randomly selected as the control area, and after training, dressing is done daily and on days 1-3-7-14-21-28 using criteria bates-jensen tests and wound healing status are examined.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khumeini Hospital Complex

Full name of responsible person

Ahmad Reza Taheri

Street address

Tehran, Keshavarz blvd, Valiasr hospital, Plastic department

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Futuhi

Street address

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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

Hamed Shahdadi

Position

Fellow

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hamed Shahdadi

Position

Fellow

Latest degree

Specialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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

All data will be released after de-identification

When the data will become available and for how long

the access period starts 6 months after the results are published

To whom data/document is available

all researchers

Under which criteria data/document could be used

By mentioning the source, it is possible to analyze the

data

From where data/document is obtainable

Request from the responsible author

What processes are involved for a request to access

data/document

Upon request, the data will be sent by e-mail within one month

Comments