

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Zataria multiflora cream on split-thickness skin graft donor site management: A randomized, blinded, placebo-controlled clinical trial

Protocol summary

Study aim

- Determining the therapeutic effect of Zataria multiflora cream in the wound healing process at the skin graft site

Design

Clinical trial with control group, with parallel groups, triple blind, randomized, phase 3 on 27 patients

Settings and conduct

From the first of 23 september 2021 to 22 October 2021 for a month in Valiasr Hospital and dermatology Hospital of Razi in Tehran (third level hospital) will be performed. All stages of the study are in line with the protocol of the approved ethics in the research of the ethics committee of Tehran University of Medical Sciences and written informed consent will be received from all participants.

Participants/Inclusion and exclusion criteria

Patients who will have a skin graft removed from their thighs to treat trauma, wounds, tumors or burns will be included in this study.

Intervention groups

Patients who qualify for the study will undergo surgery after complete anesthesia. The skin graft site is disinfected with 10% betadine solution and is prepared from two adjacent areas (at a distance of one centimeter) with dimensions equal to the graft tissue. All skin grafts 0.4 mm thick from the antero-lateral region of the thigh are prepared by electric dermatome. Shirazi thyme cream treatment (group A) will be used randomly in one of the two skin graft sites and placebo treatment will be used in the other place (base cream without thyme extract, group B). Thyme cream and placebo cream are similar in appearance, weight, color and consistency and can only be identified by codes A and B.

Main outcome variables

Age Gender Wound size Wound depth Wound edges The degree of wound weakness Type of necrotic tissue The amount of necrotic tissue Exudate Type Exudate rate The color of the skin around the wound Tissue edema around the wound Induration Granulation Epithelialization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210624051695N1**

Registration date: **2021-07-08, 1400/04/17**

Registration timing: **prospective**

Last update: **2021-07-08, 1400/04/17**

Update count: **0**

Registration date

2021-07-08, 1400/04/17

Registrant information

Name

mohsen mahmoodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5540 0864

Email address

draref64@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Zataria multiflora cream on split-thickness skin graft donor site management: A randomized, blinded, placebo-controlled clinical trial

Public title

The effects of Zataria multiflora cream on split-thickness skin graft donor site

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing skin graft removal from the thigh for trauma treatment Patients undergoing skin graft removal from the thigh to treat wounds Patients undergoing skin graft removal from the thigh to treat tumors Patients undergoing skin graft removal from the thigh to treat burns

Exclusion criteria:**Age**

To **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

Shirazi thyme cream treatment (group A) will be used randomly in one of the two skin graft sites and in the other place placebo treatment (thyme extract base cream, group B) will be used. Thyme cream and placebo cream are similar in appearance, weight, color and consistency and can only be identified by codes A and B. The random selection sequences of groups A and B are calculated by a statistician and methodologist and maintained by a person who has no other interest or participation in the design. The researchers and the subjects and the statistical analyst will be blind to the content of the ointment throughout the study and during the statistical analysis.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The random selection sequences of groups A and B are calculated by a statistician and methodologist and maintained by a person who has no other interest or participation in the design. Researchers and subjects and statistical analysts will be blind to the content of the ointment 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 Tehran University of Medical Sciences

Street address

Unit 3, No 176, Makhsoos Street, Qazvin Square

City

tehran

Province

Tehran

Postal code

1333955833

Approval date

2021-07-06, 1400/04/15

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.135

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

Wound healing

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

Wound changes according to Bates-Jensen criteria

Timepoint

On days 7, 14, 21 and 28 after surgery

Method of measurement

Bates-Jensen criteria

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Zataria multiflora Cream, Barij Essence pharmaceutical Company, contains Zataria multiflora essential oil based on 0.02 to 0.033% of thymolol in the product

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Educational and Medical Center

Full name of responsible person

Mohsen Mahmoodi

Street address

Unit 3, No 176, Makhsoos Street, Qazvin square

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeean

Street address

Unit 3, No 176, Makhsoos Street, Qazvin Square

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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

Mohsen Mahmoodi

Position

Plastic Surgery Assistant

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any analysis of the delivered data is allowed

From where data/document is obtainable

Applicants can contact draref64@gmail.com.

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

by Email

Comments