

# 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1333955833

**Phone**

+98 21 5540 0864

**Email**

draref64@gmail.com

## 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

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohsen Mahmoodi

**Position**

Plastic Surgery Assistant

**Latest degree**

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## Person responsible for updating data

### Contact

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Tehran University of Medical Sciences

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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**