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 Indoration 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
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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 analyst

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.

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeean
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Email
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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
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Person responsible for updating data

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Tehran University of Medical Sciences
Full name of responsible person
Mohsen Mahmoodi
Position
Plastic Surgery Assistant
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**