Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of effects of calcipotriol ointment on healing of split thickness skin graft donor site: a single blind controlled trial

Protocol summary

Study aim
Evaluation of effects of calcipotriol ointment on healing of the split thickness skin graft donor site
Design
Parallel group, single blind, randomized controlled trial
Settings and conduct
This study is a randomized single blind clinical trial which will be conducted in a burn ward of a teaching hospital. In patients that have two different donor sites each site will randomly assigned to the intervention or control group. In patients that have one donor site each half will be assigned to the intervention or control group. Outcomes will be assessed three, six, eight and ten days after the intervention. Assessor of the primary and secondary outcomes and Data analyzer will not have any information about the allocation of donor sites to each group.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients older than 18 years old who sign informed consent form will be recruited. Exclusion criteria: donor site infection or bleeding; hypercalcemia; hyperphosphatemia; renal failure, hepatic impairment; sepsis; pregnancy and lactation
Intervention groups
Intervention group: Beside standard cares, the calcipotriol ointment 0.005% will be applied topically on the donor site every other day for ten days. Control group: Participants will only receive the daily standard cares of the donor site for ten days.
Main outcome variables
Percent of epithelialization of the donor site; Number of episodes of infection and bleeding of the donor site

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150609022637N5**
Registration date: **2018-08-27, 1397/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-27, 1397/06/05**
Update count: **0**
Registration date
2018-08-27, 1397/06/05

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-06-22, 1397/04/01
Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of effects of calcipotriol ointment on healing of split thickness skin graft donor site: a single blind controlled trial

Public title

Evaluation of effects of calcipotriol ointment on healing of skin graft donor site

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergo split thickness skin graft Patients sign informed consent form

Exclusion criteria:

Infection of the donor site Bleeding of the donor site Pregnancy Lactation Hypercalcemia Hyperphosphatemia Renal failure Hepatic impairment Sepsis

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

More than 1 sample in each individual

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

If Participants have two symmetric donor sites (e.g. left and right thigh), one of the donor sites will be allocated to the intervention group and the other site will be allocated to the control group. If participants have only one donor site, one-half of the site will be allocated to the intervention group and the other half will be allocated to the control group.

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The investigator who inspect the donor site regarding infection, bleeding and healing will be blinded in the following way: patient or one of his/her caregivers will apply the ointment every other day at morning. On the third day the donor site will be evaluated 4 to 6 hours after the ointment application, when the ointment has completely been absorbed and the intervention and control sites will not be different in this regard. The other times of the evaluation will be one day after the application of the ointment. Again the ointment has completely been absorbed and the intervention and control sites will not be different in this regard. Investigator who will statistically analyze data will not have any information about the source (intervention or control group) of data. Other investigators, patients and nurses will not be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Office of the Vice Chancellor for Research, Ebne-sina Ave, Jahad Blvd

City

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Province

Kerman

Postal code

7619813159

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.KMU.REC.1397.060

Health conditions studied

1

Description of health condition studied

Burn injury

ICD-10 code

T30

ICD-10 code description

Burn and corrosion, body region unspecified

Primary outcomes

1

Description

Percent of epithelialization of the donor site

Timepoint

10 days after the intervention

Method of measurement

Calculation of the ratio of the surface area of the epithelialized parts to the total surface area of the donor site

Secondary outcomes

1

Description

Number of episodes of the donor site infection

Timepoint

Before the intervention and 3, 6, 8 and 10 days after the intervention

Method of measurement

Inspection of the donor site and/or microbial culture of wound secretions

2

Description
Number of episodes of the donor site bleeding
Timepoint
Before the intervention and 3, 6, 8 and 10 days after the intervention
Method of measurement
Inspection of the donor site

Intervention groups

1

Description
Intervention group: Calcipotriol ointment 0.005% (Tehran Shimi Company) will be applied topically on the donor site every other day for 10 days.
Category
Treatment - Drugs

2

Description
Control group: No intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa hospital
Full name of responsible person
Ali Parand
Street address
Shafa hospital, Shafa Ave., Jomhoori Blvd.
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Sponsors / Funding sources

1

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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
Kerman 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
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Naemeh Nikvarz
Position
Assistant professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable