Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative result of graft take in 2 different methods for burn patient with old and infected granulation tissue in Ghotbeddin hospital at 2009 and 2010

Protocol summary

Summary

Nowadays, old granulation tissue is one of the important problems in the management of burn patients. As hydrogen peroxide and amnion membrane have antibacterial effects, this survey is planned to compare result of graft taking in using these agents. 90 patients aged 15-60 years with two limbs involvement and old infected wounds, according to the surgeon's diagnosis, are enrolled. Patients with age more than 60 years, Albumin less than 2.5, and underlying diseases such as cardiovascular diseases, diabetes mellitus, or psychiatric disorders are excluded. Patients are divided into two groups (hydrogen peroxide and amnion groups). All wounds are debrided. Then, in the hydrogen peroxide group, left arm wounds are grafted after debridment (control) while in right arm, hydrogen peroxide soaked gauze is applied for 5 minutes then the site is irrigated and the graft is applied (intervention). In the amnion group, wound in left arm is grafted after debridment and wounds in right arm is covered with amnion after debridment and grafting (intervention). The dressings are removed 5 days later for the first time then changed every other day. Follow-up visit are two weeks after surgery and percentage of graft taking are assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808301605N6**
Registration date: **2010-04-17, 1389/01/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-04-17, 1389/01/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Vice chancellor for Research

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-06-21, 1389/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative result of graft take in 2 different methods for burn patient with old and infected granulation tissue in Ghotbeddin hospital at 2009 and 2010

Public title

Comparative result of graft take in 2 different methods for burn patient with old and infected granulation tissue in Ghotbeddin hospital at 2009 and 2010

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age 15-60 years, involvement of two with old and infected wounds, passing two weeks from granulation tissue formation for any reason. Exclusion: Albumin less than 2.5, patients with underlying diseases such as cardiovascular disease, diabetes mellitus, or psychiatric disorders.
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Blvd.
City
Shiraz
Postal code
Approval date
2010-02-17, 1388/11/28
Ethics committee reference number
CT-88-4773

Health conditions studied

1

Description of health condition studied
treatment of burn wound with old and infected granulation tissue
ICD-10 code
T20,T21,T2
ICD-10 code description
Burns and corrosions

Primary outcomes

1

Description
percentage of grafttake
Timepoint
2 weeks after operation
Method of measurement
determination of graftake by meter

Secondary outcomes

empty

Intervention groups

1

Description
intervention group 1: deressing of skin graft with amnion after debridment and skin graft
Category
Treatment - Surgery

2

Description
intervention group 2: applying hydrogen peroxide 2% on the wound before the skin graft
Category
Treatment - Surgery

3

Description
control group: wound excision and skin graft
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghotbeddin Hospital
Full name of responsible person
Ali akbar Mohammadi
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Fakhrabad Street, Ghotbeddin Hospital
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellorship for Research, Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Hossein Dabbaghmanesh
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Vice-chancellorship for Research, Shiraz University of Medical Sciences, Zand Blvd.
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Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellorship for Research, Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty