

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 debridement (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 debridement and wounds in right arm is covered with amnion after debridement 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

Name

Ali Akbar Mohammadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

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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 grafttake by meter

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1: deressing of skin graft with amnion after debridement 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

Street address

Fakhrabad Street, Ghotbeddin Hospital

City

Shiraz

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

Street address

Vice-chancellorship for Research, Shiraz University of Medical Sciences, Zand Blvd.

City

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**Contact****Name of organization / entity**

Shiraz Burn Reaserch Center

Full name of responsible person

Ali Akbar Mohammadi

Position

General Surgeon. Assistant Professor

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz Burn Reaserch Center

Full name of responsible person

Ali Akbar Mohammadi

Position

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Other areas of specialty/work**Street address**

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz Burn Reaserch Center

Full name of responsible person

Masoomeh Kherad

Position

manager of Shiraz Burn Reaserch Center/Bachelor of Science

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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