

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of effect of amniotic membrane on split-thickness skin fixation in patient with extremities burns in ghotbeddin hospital

Protocol summary

Summary

Fifty four patients (108 limbs) with deep 2nd and 3rd degree burns included in a prospective clinical trial. All patients needed split-thickness skin graft for burn wound coverage. We selected the patients who had symmetric burns on two (upper or lower) extremities, and then the extremities were randomly assigned into two groups. In one limb, the skin graft traditionally fixed with skin staples (control group) but in the other limb the skin graft fixed with amniotic membrane (amnion group). In the amnion group, the graft was inserted on the wound bed, the amniotic membrane was wrapped around the grafted extremity and dressing was applied. The membrane adheres to itself when wrapped around the extremity and there is no need to any stitch or staple. On the 5th post-op day, in both groups, the dressings were removed, the wound was irrigated with normal saline, the skin graft was covered with sterile Vaseline gauze and again dressing was applied. This changing dressing continued every other day till the complete graft take was achieved. The duration and success rate of complete graft take were compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902281605N9**

Registration date: **2010-06-12, 1389/03/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-12, 1389/03/22

Registrant information

Name

Ali Akbar Mohammadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1621 6097

Email address

mohamadiaa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Vice chancellor for Research

Expected recruitment start date

2008-10-01, 1387/07/10

Expected recruitment end date

2010-01-20, 1388/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of amniotic membrane on split-thickness skin fixation in patient with extremities burns in ghotbeddin hospital

Public title

Evaluation of effect of amniotic membrane on split-thickness skin fixation in patient with extremities burns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Deep 2nd and 3rd degree burns; symmetric burns on two (upper or lower) extremities, candidates for split-thickness skin graft
Exclusion criteria: age more than 60, history of cardiac disease,

renal failure, diabetes mellitus, any other severe underlying metabolic disorder

Age
From **13 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Amniotic membranes were retrieved from elective cesarean sections of mothers without any sexually transmitted disease, endometritis, premature rupture of the membranes or meconium stained amniotic fluid. The amnion is carefully separated from chorion and placenta and washed thoroughly with normal saline until a whitish, smooth, transparent layer remains, which is then stored in normal saline-gentamicin solution at 4°C. If HIV, HBS, HCV and VDRL tests are negative for both mother and umbilical cord, the amniotic membrane will be used. Routine cultures are obtained from stored membranes to rule out bacterial contamination

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

2010-03-10, 1388/12/19

Ethics committee reference number

CT-88-01-01-1634

Health conditions studied

1

Description of health condition studied

skin graft

ICD-10 code

T86.8

ICD-10 code description

Failure and rejection of other transplanted organs and tissues

Primary outcomes

1

Description

percentage of grafttake

Timepoint

2 weeks after operation

Method of measurement

determination of grafttake by meter

2

Description

grafttake time

Timepoint

every other day

Method of measurement

time between operation and grafttake

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: In the amnion group, the graft was inserted on the wound bed, the amniotic membrane was wrapped around the grafted extremity and dressing was applied. The membrane adheres to itself when wrapped around the extremity and there is no need to any stitch or staple. On the 5th post-op day, in both groups, the dressings were removed, the wound was irrigated with normal saline, the skin graft was covered with sterile Vaseline gauze and again dressing was applied. This changing dressing continued every other day till the complete graft take was achieved.

Category

Treatment - Surgery

2

Description

Control : wounds are grafted with split thickness method by using stapler to fix

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Burn reaserch center;Ghotb-eddin Burn Center

Full name of responsible person

Ali Akbar Mohammadi

Street address

Burn reaserch center, Fakhrabad Street, Shiraz .

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research

Full name of responsible person

Mohammad Hossein Dabbaghmanesh

Street address

Vice-chancellor of Research, Shiraz University of Medical Sciences

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for Research

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 University of Medical Sciences

Full name of responsible person

Ali Akbar Mohammadi

Position

Assistant Professor, General Surgeon

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

Fakhrabad Street, Shiraz

City

Shiraz

Postal code**Phone**

+98 71 1821 9638

Fax**Email**

mohamadiaa@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Burn reaserch center, Shiraz University of Medical Sciences,

Full name of responsible person

Ali Akbar Mohammadi

Position

Assistant Professor, General Surgeon

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

Shiraz Burn Research Center, Ghotbeddin Hospital, Fakhrabad St.

City

Shiraz

Postal code**Phone**

+98 71 1821 9638

Fax**Email**

mohamadiaa@sums.ac.ir

Web page address

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 nursing

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

Fakhrabad St., Ghotbeddin Hospital, Shiraz Burn Reaserch Center

City

Shiraz

Postal code**Phone**

+98 71 1820 8880

Fax**Email**

burnres1@sums.ac.ir

Web page address

www.burnres.sums.ac.ir

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