Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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 graftake by meter

2

Description
graftake time

Timepoint
every other day

Method of measurement
time between operation and graftake

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-chanceller of Research, Shiraz University of Medical Sciences
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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-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
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Masoomeh Kherad
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manager of Shiraz Burn Reaserch Center/Bachelor of nursing
Other areas of specialty/work
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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