

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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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*