

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of Outcomes of Amniotic Membrane Dressing with Conventional Dressing in Donor Graft Site of Patients with Donor Site of Patients Admitted in Mousavi Hospital, Zanjan

Protocol summary

Study aim

Comparison of the results of two dressing methods with amniotic membrane and classic dressing at the site of harvest in patients admitted to Ayatollah Mousavi Hospital in Zanjan

Design

Randomized clinical trial with control group, single center

Settings and conduct

This research will be conducted in Ayatollah Mousavi Hospital in Zanjan in 1399 as a randomized clinical trial of futuristic two-way blindness in 1398 on patients who have suffered burns or need to be half-skinned due to another disease.

Participants/Inclusion and exclusion criteria

Inclusion patients who need a semi-thick skin graft for another reason and have a donor site Donor location in the limbs No injuries other than burns General physical and mental health 7 years and 60 years Trauma, are less than 40 percent of the wound Exclusion Patients with blood-borne viral infections Dissatisfaction of patients Lack of follow-up Presence of any cerebrovascular alcohol and drug abuse use of antibiotics use of steroids Infected patients

Intervention groups

Patients are randomly divided into two groups: the recipient of the classic dressing (Vaseline gas) at the donor site and the amniotic membrane at the donor site.

Main outcome variables

Oscar percentage Healing rate Wound healing process Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200615047782N1**

Registration date: **2020-07-09, 1399/04/19**

Registration timing: **prospective**

Last update: **2020-07-09, 1399/04/19**

Update count: **0**

Registration date

2020-07-09, 1399/04/19

Registrant information

Name

Salman Sotoudeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 1000

Email address

salman_1238@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Outcomes of Amniotic Membrane Dressing with Conventional Dressing in Donor Graft Site of Patients with Donor Site of Patients Admitted in Mousavi Hospital, Zanjan

Public title
Effect of Amniotic Membrane Dressing in Donor Graft Site

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with second- or third-degree burns or patients who need a semi-thick skin graft for any other reason and have a donor site Donor location in the limbs No injuries other than burns General physical and mental health Age between 7 years and 60 years Other conditions, such as trauma, are less than 40 percent of the wound and are on the limb and need to be removed

Exclusion criteria:

Patients with blood-borne viral infections including hepatitis B and C and HIV Dissatisfaction of patients to enter the study Lack of follow-up ability Presence of any cerebrovascular, cardiovascular, endocrine, liver and kidney diseases; Pregnancy History of alcohol and drug abuse Concomitant use of antibiotics (orally and topically) Concomitant use of steroids or immunosuppressive drugs Infected patients at the donor site

Age

From **7 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

We will assign participants in study group using random blocks (each block size =4). Considering A and B as interventions for participants, we could have six blocks each have 2 A and 2 B (AABB, ABAB, ABBA, BABA, BBAA, BAAB). Ten block will be selected randomly (by rand function of Microsoft Excel) and we will recruits the participants according to final order.

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

Zanjan University of Medical Sciences Ethics Committee

Street address

Ayatollah Mousavi Hospital

City

Zanjan

Province

Zanjan

Postal code

11345678

Approval date

2020-04-29, 1399/02/10

Ethics committee reference number

IR.ZUMS.REC.1399.056

Health conditions studied

1

Description of health condition studied

Patients suffered thermal burns in need skin graft

ICD-10 code

X09

ICD-10 code description

Exposure to unspecified smoke, fire and flames

Primary outcomes

1

Description

Scar percentage

Timepoint

The amount of scar on the fifth, fourteenth, and finally thirty-sixth days is evaluated as outpatient in the clinic by the relevant professor and its amount is recorded with a qualitative scale of 4 items: excellent, good, average, weak.

Method of measurement

A measure of the body's scar level that is measured objectively

2

Description

Healing rate

Timepoint

The time required for wound healing on the fifth, fourteenth, and finally 30th days of the clinic is evaluated on an outpatient basis by the relevant professor and its amount is recorded with a qualitative scale of 4 items: excellent, good, average, weak.

Method of measurement

Healed: the wound area where the medicine was applied is completely healed Obviously Effective: 70 % of the wound is healed Effective: over 30 % of the wound is healed Ineffective: the effective standard is not met

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention sites with a thickness of 0.4 to 0.6 mm are given using an electric dermatome with the same level of oxidation; Bleeding is controlled using epinephrine 1 in 50,000 with sterile gauze. One of the donor sites is randomly covered with an amniotic membrane. Amniotic membrane is taken from sero negative mothers who accepted to deliver their tissue as Volunteer. Then biologic dressing is covered by sterile gauze.

Category

Treatment - Other

2

Description

Control group: The control group of control locations are both given a thickness of 0.4 to 0.6 mm using an electric dermatome with equal levels in both groups of oxions; Bleeding is controlled using epinephrine 1 in 50,000 with sterile gauze. One of the donor sites is accidentally covered with ordinary dressing, ie Vaseline gas (control group). In the control group, the cover is done directly with Vaseline gas. In the control group, the dressing is done with Vaseline gas and it will not be touched for 5 days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Mohammad Hossein Moghimi

Street address

Ayatollah Mousavi Hospital

City

Zanjan

Province

Zanjan

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11234567

Phone

+98 24 3313 0001

Email

salman_1238@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

Street address

Zanjan University of Medical Sciences, Gavazang road

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Province

Zanjan

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1123456789

Phone

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Email

shoghli@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mohammad Hosein Moghimi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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1123456789

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Person responsible for scientific

inquiries

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Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as the original or similar information, can be shared

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only scientific use of data is possible

From where data/document is obtainable

Salman sotoudeh Salman_1238@yahoo.com

What processes are involved for a request to access data/document

Data files will be received by the applicant within a maximum of three days

Comments