Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 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 wasapplied is completely healed ObviouslyEffective: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 strile 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

Postal code
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

City
Zanjan

Province
Zanjan

Postal code
1123456789

Phone
+98 24 3313 0001

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

Street address
Mousavi hospital, Gavazang road

City
Zanjan

Province
Zanjan

Postal code
1123456789

Phone
+98 24 3310 0001

Email
Mohammadhosein_moghimi@yahoo.com

Person responsible for scientific

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

Street address
Mousavi hospital, Gavazang road

City
Zanjan

Province
Zanjan

Postal code
1123456789

Phone
+98 24 3313 0001

Email
Mohammadhosein_moghimi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Mohammad Hossein Moghimi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

Street address
Mousavi hospital, Gavazang road

City
Zanjan

Province
Zanjan

Postal code
1123456789

Phone
+98 24 3313 0001

Email
Mohammadhosein_moghimi@yahoo.com

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