Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

comparison of short-term outcomes between amniotic membrane and conventional dressing in skin graft Donor site in patients hospitalized in the burn ward of Imam Khomeini Hospital of Urmia in 2019

Protocol summary

Study aim
Comparison of short-term outcome of amniotic membrane dressing versus routine dressing in donor graft site in burn patients in Urmia Imam Khomeini Hospital in 2019

Design
A quasi-experimental trial without a randomization process in which 26 donor sites received different dressings on both sides of the body.

Settings and conduct
This clinical trial study will be carried out in the burn ward of Imam Khomeini Hospital of Urmia in 2019. The patient in intervention group will be treated with amniotic membrane dressing (left side of the patient) and topical antimicrobial dressing (right side of the patient). Patients in control group on the right side will be treated with nitrofurazine-impregnated gauze and 2 g of ointment for each percent of the graft site, and the left side will be dressed by amniotic membrane. The desired variables for all patients will be extracted through a questionnaire designed for this purpose.

Participants/Inclusion and exclusion criteria
Exclusion criteria: patients with underlying diseases (diabetes, Renal failure, hepatitis, immune deficiency and cardiovascular disease) ;Inclusion criteria: All persons aged between 1 to 66 years

Intervention groups
intervention group: amniotic membrane dressing in the left side of patient, control group:nitrofurazone dressing in the right side of the patient.

Main outcome variables
scar status and wound epithelization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190614043889N1**
Registration date: **2020-02-13, 1398/11/24**
Registration timing: **retrospective**

Last update: **2020-02-13, 1398/11/24**
Update count: **0**

Registration date
2020-02-13, 1398/11/24

Registrant information

Name
jafar kazemzade

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3345 9538

Email address
jafarkazemzade48@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-04, 1398/03/14

Expected recruitment end date
2019-12-05, 1398/09/14

Actual recruitment start date
2019-06-04, 1398/03/14

Actual recruitment end date
2020-01-04, 1398/10/14

Trial completion date
2020-01-04, 1398/10/14

Scientific title
comparison of short-term outcomes between amniotic membrane and conventional dressing in skin graft Donor

site in patients hospitalized in the burn ward of Imam Khomeini Hospital of Urmia in 2019

Public title
Comparison of between amniotic membrane and conventional dressing outcomes in burned skin graft Donor site
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patient age 1-66 years old Patient accept biologic dressing Burns require skin grafts regardless of burning percent
Exclusion criteria:
have underlying disease such as diabetes mellitus renal failure hepatitis vascular in sufficiency and heart disease patient have other trauma
Age
From **1 year** old to **66 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **26**
More than 1 sample in each individual
Number of samples in each individual: **2**
comparison of graft donor site in left and right side
Actual sample size reached: **26**
More than 1 sample in each individual
Actual sample size in each individual: **2**
comparison of graft donor site in left and right side
Randomization (investigator's opinion)
N/A
Randomization description
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
Ethics Research Commity Of Urmia Medical university
Street address
ershad ave emam khomeini hospital born ward
City
Urmia
Province
West Azarbaijan
Postal code
5715718516
Approval date
2019-06-02, 1398/03/12
Ethics committee reference number
ir.umsu.rec.1398.081

Health conditions studied

1

Description of health condition studied
Burn. Donor Graft Side
ICD-10 code
T30.0
ICD-10 code description
Burn of unspecified body region, unspecified degree

Primary outcomes

1

Description
Epithelialization and scar in donor graft site
Timepoint
effect of Biologic dressing in donor graft site on days 7, 14 and 30
Method of measurement
Information Gathering Form

Secondary outcomes

1

Description
Local infection rate
Timepoint
over a period of one month
Method of measurement
observed local infection

2

Description
Amount of pain
Timepoint
during a period of one month
Method of measurement
Visual Analogue Scale

3

Description
Patients' rate of co-operation in dressing replacement
Timepoint
during a period of one month
Method of measurement
observation

4

Description
Duration of recovery time
Timepoint
over a period of one month
Method of measurement
week

5

Description
itching rate
Timepoint
during a period of one month
Method of measurement
to measure with Nominal Scale (yes/no)

Intervention groups

1

Description
Intervention group: the patient's left side will be dressed biologically with amniotic membrane.
Category
Treatment - Surgery

2

Description
Control group:The right side of the patient is dressed with Nitrofurazone impregnated gas and 2 grams of ointment will be used for each percentage of the graft site
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Burn Center of Imam Khomeini Hospital in Urmia
Full name of responsible person
Dr. Jafat Kazemzadeh
Street address
Ershad ave Emam Khomeini hospital
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URMIA
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5715718516
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+98 44 3198 8111
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jafarkazemzade48@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Jafar Kazemzade
Street address
Ershad ave emam khomeini hospital
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URMIA
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jafar.kazemzade48@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Jafar Kazemzadeh
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Medical Education
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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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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

Not applicable

Title and more details about the data/document

Data related to the primary and secondary outcomes will be provided to clinical researchers in full detail after unidentifiable individuals and articles are published.

When the data will become available and for how long

Up to 6 months after publishing resultes

To whom data/document is available

Researchers, Ethics Committee

Under which criteria data/document could be used

cite of clinical results in other similar researches and collaborating with other large multi center clinical trials with approval ethical commite and IRCT center.

From where data/document is obtainable

The results are available in the form of articles and seminars to applicants and can be contacted by Dr. Jafar Kazemzadeh, Imam Hospital Burn Unit. Urmia.Imam Hospital. Burn Section.Jafar Kazemzadeh. Contact No. 098 44 33459539

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

The applicant can access the results of the study by written request or by contacting the center within a maximum of 10 working days.

Comments