Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of human amniotic membrane on wound healing of donor site in burn patients compared with standard treatment

Protocol summary

Study aim
Evaluation of human amniotic membrane on wound healing of donor site in burn patients

Design
The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized

Settings and conduct
The aim of this study is to evaluate the effect of human amniotic membrane on wound healing in burn patients referred to the burn ward of Vasei hospital in Sabzevar. None of the patients and outcome evaluators are aware of the study procedure and placement of the study groups. Before graft removal, patients are randomly divided into two groups: proximal or distal intervention area and in each group according to the intervention area, the other is considered as a control. Evaluation of response to treatment is performed on days 10, 20 and 30 after intervention using photographic morphometry for both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 2-60 years. Grade 2 and 3 burns require autologous skin graft and surgery. Exclusion criteria: Connective tissue diseases, diabetes, malnutrition, septicemia, heart disease, kidney failure, cancer, chemotherapy and the use of corticosteroid drugs. Dissatisfaction patients to participate in the study.

Intervention groups
Intervention group: donor site in this group was covered with amniotic membranes made by Royan Cells Co 10 x 15 cm, Vaseline gauze, and wet dressing. Control group: The patients' graft site was just covered with Vaseline gauze and wet dressing.

Main outcome variables
Determination of donor wound epithelization, pigmentation, granulation and superfacial vascularity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181006041252N14**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **retrospective**

Last update: **2019-08-26, 1398/06/04**
Update count: **0**

Registration date
2019-08-26, 1398/06/04

Registrant information

Name
Mohammad Sahebkar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4401 8337

Email address
sahebkarm@medsab.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-04-20, 1395/02/01

Expected recruitment end date
2017-04-21, 1396/02/01

Actual recruitment start date
2016-06-25, 1395/04/05

Actual recruitment end date
2017-01-24, 1395/11/05

Trial completion date
2017-02-23, 1395/12/05

Scientific title
Evaluation of human amniotic membrane on wound healing of donor site in burn patients compared with standard treatment

Public title
Evaluation of the effect of amniotic membrane on wound healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 2-60 years Grade 2 and 3 burn patients require autologous skin graft (STSG) and surgery
Exclusion criteria:
Connective tissue diseases, diabetes, malnutrition, septicemia, heart disease, kidney failure, cancer, chemotherapy and the use of corticosteroid drugs. Dissatisfaction patients to participate in the study.
Age
From **2 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **35**
Actual sample size reached: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization was performed using the card in a way that 35 cards were produced and divided into 17 with proximal and 18 with distal name. These cards were poured into a bowl and shuffled, then the cards drew without replacement from the bowl and aligned from 1 to 35 respectively. By drawing each card and identifying the proximal or distal part as the intervention, the other part was considered as a control.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study was a double-blind study in which no patients and outcome evaluators were aware of the study procedure and placement of the study groups and each person in the study will be assigned to "A" and "B" code that only the researcher will know about the type of group
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Approval date
2016-06-25, 1395/04/05
Ethics committee reference number
IR.MEDSAB.REC.1395.44

Health conditions studied

1

Description of health condition studied
Burn
ICD-10 code
M61.30
ICD-10 code description
Calcification and ossification of muscles associated with burns, unspecified site

Primary outcomes

1

Description
Determination of pigmentation
Timepoint
Measurement of pigmentation on days 10, 20 and 30 after the intervention
Method of measurement
Photographic Morphometry

2

Description
Determination of epithelization
Timepoint
Measurement of epithelization on days 10, 20 and 30 after the intervention
Method of measurement
Photographic Morphometry

3

Description
Determination of superficial vascularity
Timepoint
Measurement of superficial vascularity on days 10, 20 and 30 after the intervention
Method of measurement
Photographic Morphometry

4

Description
Determination of granulation
Timepoint
Measurement of granulation on days 10, 20 and 30 after the intervention
Method of measurement
Photographic Morphometry

Secondary outcomes

1

Description
Determine the amount of pain
Timepoint
Measurement of pain on days 10, 20 and 30 after the intervention
Method of measurement
Visual Analogue Scale of Pain Questionnaire

Intervention groups

1

Description
Intervention group: donor site in this group was covered with amniotic membranes made by Royan Cells Co 10 x 15 cm, Vaseline gauze, and wet dressing.
Category
Treatment - Other

2

Description
Control group: The patients' graft site was just covered with Vaseline gauze and wet dressing.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Vasei hospital
Full name of responsible person
Mohammad Sahebkar
Street address
Vasei Hospital, Asadabady Ave., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 1014
Email
Vaseih@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Dr. Fereshte Ghorat
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8319
Email
Drghorat@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Mohammad Sahebkar
Position
Consultant
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code

9617913114

Phone

+98 51 4401 8337

Email

Mohammad.sahebkar66@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mojtaba Vaheb

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cosmetic Plastic Surgery

Street address

Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 1604

Email

Drvaheb2017@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Sahebkar

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 8337

Email

Mohammad.sahebkar66@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available