

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 superficial 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