

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Bio-compatible wound dressing for repairing skin lesions: Trauma, Burn, and Cancer: A Clinical Trial

Protocol summary

Study aim

The purpose of this study was to compare the results of the control group with the group of simultaneous wound transplantation in patients with grade 1, 2 and 3 burns and patients with diabetic foot ulcer and trauma less than 5 cm wide.

Design

A clinical trial with a community-based, pragmatic control group with parallel, randomized groups

Settings and conduct

Patients from Skin Research Center of Shahid Beheshti University will candidate by dermatologist. Lesion of skin will dress and progress by 14 days will be control by expert.

Participants/Inclusion and exclusion criteria

Including criteria: Skin lesions due to Trauma, Burn, and Cancer Excluding criteria: Patients with autoimmune diseases Patients with skin diseases Patients with skin related infectious diseases

Intervention groups

Intervention 1: Wound healing with dead tissue removal and early transplantation with autologous PRGF gel and evaluation until day 14 post-transplantation. Intervention 2: Control group, with conventional treatment. In both groups, open the dressing on the fifth day after surgery, the wound was washed with normal saline and covered with sterile Vaseline gas and re-dressed. Changing the dressing will continue for one day until the transplant is complete.

Main outcome variables

Repaired wound

General information

Reason for update

Acronym

SLR

IRCT registration information

IRCT registration number: **IRCT20190826044620N1**

Registration date: **2020-01-18, 1398/10/28**

Registration timing: **prospective**

Last update: **2020-01-18, 1398/10/28**

Update count: **0**

Registration date

2020-01-18, 1398/10/28

Registrant information

Name

Mostafa Rezaei Tavirani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 9787

Email address

tavirani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bio-compatible wound dressing for repairing skin lesions: Trauma, Burn, and Cancer: A Clinical Trial

Public title

Repairing skin lesions

Purpose

Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Skin lesions due to Trauma, Burn,
Exclusion criteria:
Autoimmune diseases Skin diseases Skin related
infectious diseases

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **6**

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 committee of Shahid Beheshti University of
Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-07-21, 1398/04/30

Ethics committee reference number

IR.SBMU.REC.1398.059

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T31.0

ICD-10 code description

Burns involving less than 10% of body surface

2

Description of health condition studied

Superficial burns

ICD-10 code

T31

ICD-10 code description

Burns classified according to extent of body surface
involved

3

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

4

Description of health condition studied

trauma

ICD-10 code

S31.1

ICD-10 code description

Open wound of abdominal wall without penetration into
peritoneal cavity

Primary outcomes

1

Description

Wound quality

Timepoint

3 days

Method of measurement

expert visit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention in the intervention group: Six people with
skin lesions less than 5 cm in size. Use of autologous
growth factor-rich plasma in gel form, bio compatible
Scaffold coating in both groups, opens the fifth day after
surgery, the wound is washed with normal saline and
covered with sterile Vaseline gas and again dressed.
Changing the dressing will continue for one day until the
transplant is complete.

Category

Treatment - Surgery

2

Description

Intervention in the control group: The site of transplantation is treated in the traditional way. In both groups open the dressing on the fifth day after surgery, the wound is washed with normal saline and covered with sterile Vaseline gas and again dressed. Changing the dressing will continue for one day until the transplant is complete.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti university of Medical sciences, Skin Research Center

Full name of responsible person

Dr. Hamideh Moravvej

Street address

skin research center, Shohada Hospital, Tajrish

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1989934148

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Darband St., Qods Sq.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mostafa Rezaei Tavirani

Position

Director of Center

Latest degree

Ph.D.

Other areas of specialty/work

Proteomics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Informatics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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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

Type and dimension of wound

When the data will become available and for how long

One year

To whom data/document is available

Research delegates

Under which criteria data/document could be used

Supervision

From where data/document is obtainable

Mostafa Rezaei Tavirani

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

email

Comments