Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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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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Medical Informatics

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Person responsible for updating data

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Full name of responsible person

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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