

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Effects of the acellular dermal matrix on skin wound healing: A pilot clinical trial study

Protocol summary

Study aim

Determination and comparison of adhesion and stem cell growth in the two groups.

Design

In order to conduct the present study, 15 people with skin lesions and wounds will be selected. The results will be compared between different groups using statistical software and ANOVA statistical analysis.

Settings and conduct

The skin matrix transplant will be performed by a dermatologist. All subjects will be informed of the study and a written informed consent form, based on the principles of medical ethics, will be completed by them. Sample selection - Preparation of cellular scaffold - Review of prepared cellular scaffold.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the absence of underlying diseases, the absence of autoimmune diseases, the absence of hypertension, the absence of diabetes and the willingness to participate in the study and complete the questionnaire and written informed consent. Also, people with underlying diseases, autoimmunity, high blood pressure, diabetes, etc. will be excluded from the study.

Intervention groups

We have 2 intervention groups, one group including healthy skin as the control group and one group with burns that will be transplanted as the intervention group.

Main outcome variables

1. Acellular scaffolding 2. Scaffold toxicity 3. The degree of adhesion of cells to the scaffold 4. Prepared scaffold matrix

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210112050019N1**

Registration date: **2021-08-24, 1400/06/02**

Registration timing: **retrospective**

Last update: **2021-08-24, 1400/06/02**

Update count: **0**

Registration date

2021-08-24, 1400/06/02

Registrant information

Name

Leyla Roshangar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3336 3870

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-16, 1400/03/26

Expected recruitment end date

2021-06-26, 1400/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of the acellular dermal matrix on skin wound healing: A pilot clinical trial study

Public title

Effects of the acellular dermal matrix on skin wound healing: A pilot clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with second-degree burns.

Exclusion criteria:

Existence of autoimmune diseases Existence of high blood pressure Existence of diabetes

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced blocked randomization (BBR) (Block size=4) will be used in the present study to assign the individuals to the intervention (receiving acellular dermal matrix) and control groups, respectively. The sequences generated by BBR using Random Allocation Software (RAS) will be preserved by epidemiologist and it will not be accessible/predictable for other individual involved in the study. Hence, allocation concealment will be assured. Notably, 15 individuals will be included into the each group and effectiveness of BBR on balancing the distribution of potential confounders across the study groups will be assessed.

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

Tabriz Ethics Committee of Medical Sciences

Street address

Azadi St., next to Imam Reza Hospital, Tabriz
University of Medical Sciences

City

tabriz

Province

East Azarbaijan

Postal code

51738-15992

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.TBZMED.REC.1400.248

Health conditions studied

1

Description of health condition studied

The effect of acellular skin matrix on skin wound healing

ICD-10 code

L99

ICD-10 code description

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

Primary outcomes

1

Description

Percentage of people who have burns

Timepoint

Healing of skin ulcers at the beginning of the study and 21 days after the start of the clinical trial

Method of measurement

Skin Wound Healing Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People with skin lesions due to burns, skin injuries, scar tissue caused by injuries. Initially, the cellular scaffold was prepared from the intestine and for disinfection and desullarization for 2 hours of prastic acid ./1% (C2H4O3)And 4% ethanol (C2H5OH) and 96% distilled water were used and finally the cellular scaffold was washed twice with saline phosphate buffer (PBS) and twice with distilled water. They are the manufacturer of Iranian consumables, then in the culture plate. Cell (DMEM) was placed to culture the cells, after which the dermatologist attached the cell fragments to the areas with skin lesions once to evaluate the results.

Category

Treatment - Surgery

2

Description

Control group: Does not receive any intervention.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital, Tabriz

Full name of responsible person

Dr. Mohammad Reza Ranjkesh

Street address

Azadi Street - not reached Maralan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Leila Roshanghar

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Leila Roshanghar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Histology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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

Title and more details about the data/document

By publishing an article

When the data will become available and for how long

Start access after 3 months of printing results

To whom data/document is available

Researchers and professors of all universities

Under which criteria data/document could be used

They are allowed access if there is no scientific theft

From where data/document is obtainable

If the article is published via email to the responsible author

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

In the shortest possible time after contacting the responsible author

Comments