

# 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)

###### Phone

+98 41 3336 3870

###### Email address

roshangarl@tbzmed.ac.ir

##### 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

**City**

tabriz

**Province**

East Azarbaijan

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5163639888

**Phone**

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**Email**

reza.se7en77@yahoo.com

## 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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Azadi St., Corner of Imam Reza Hospital, Tabriz  
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Reza.Se7en77@yahoo.com

**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 scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

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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**