

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of efficacy of autologous epidermal cell suspension and silver sulfadiazine ointment in treatment of second degree burn

#### Protocol summary

##### Study aim

Comparison of efficacy of autologous epidermal cell suspension and silver sulfadiazine ointment in treatment of second degree burn

##### Design

20 patients whom are burned as second degree at 2 different areas of their body will be included according to inclusion, exclusion criteria. On an area silver sulfadiazine ointment and on other one epidermal cell suspension will be applied. the study is not blinded and randomized allocation is not applied.

##### Settings and conduct

As the routine treatment of the second degree burns, we will apply silver sulfadiazine ointment every 12 hours for whole burns except the area which will be treated by epidermal cell suspension. one milliliter of the provided epidermal cell suspension is transferred to 2x2 cm of the burned area by a pipette. Then it will be compressed by a silicon mesh and a wet woven gauze and covered by a semipermeable tegaderm film. The dressing will be removed every 5 days up to 20 days and the areas will be evaluated by experienced specialist in the burns ward of Sina hospital of Tabriz University of Medical Science for reepithelization and complications. the photographs of both treated areas by silversulfadiazin and epidermal cell suspension will be obtained and finally will be compared.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All the patients who are second degree burned in at least 2 different areas of their body, admitted in Sina hospital and have no more comorbidities. Exclusion criteria: Pregnancy Milking Immunocompromised Unwilling to participate

##### Intervention groups

All the patients whom are burned as second degree in at least 2 different areas of their body

##### Main outcome variables

The percent of epithelialized skin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140705018373N2**

Registration date: **2018-03-29, 1397/01/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-29, 1397/01/09**

Update count: **0**

##### Registration date

2018-03-29, 1397/01/09

##### Registrant information

##### Name

Mohamad Reza Ranjkesh

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 116 5061

##### Email address

ranjkeshm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-05, 1396/10/15

##### Expected recruitment end date

2018-10-07, 1397/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison of efficacy of autologous epidermal cell suspension and silver sulfadiazine ointment in treatment of second degree burn

**Public title**

Autologous epidermal cells and second degree burn

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patients who are burned in 2 different areas, admitted at Sina hospital and have no more comorbidities.

**Exclusion criteria:**

Pregnancy  
Milking  
Immunocompromised  
unwilling to participate

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**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 Tabriz University of Medical Sciences

**Street address**

Sina hospital, Azadi Ave., Tabriz town, East Azarbyjan

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163639888

**Approval date**

2018-01-02, 1396/10/12

**Ethics committee reference number**

lr.tbzmed.rec.1396.833

**Health conditions studied****1****Description of health condition studied**

Second degree burn

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The percent of reepithelization of second degree burned skin

**Timepoint**

Before the intervention initiation, every 5 days till 20 days and 2 months later

**Method of measurement**

By photograph

**Secondary outcomes****1****Description**

Scar

**Timepoint**

2 months after intervention

**Method of measurement**

By photograph

**Intervention groups****1****Description**

Intervention group: The patients with at least two second degree burn areas on their body

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Dr. Mohammadreza Ranjkesh

**Street address**

Sina hospital, Azadi Ave., Tabriz town, East Azarbyjan

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**Email**

ranjkeshm@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadreza Ranjkesh

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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. Mohmmadreza Ranjkesh

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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## Person responsible for scientific inquiries

#### Contact

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Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadreza Ranjkesh

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## 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**

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**

Not applicable

### **Data Dictionary**

Not applicable