

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

City

Tabriz

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Postal code

5163639888

Phone

+98 41 3549 8236

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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Person responsible for updating data

Contact

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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