Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of therapeutic effect of dressing with skin allograft and silver sulfadiazine in deep second degree burn wounds in Zanjan Ayatollah Mousavi hospital, 2016-2017

Protocol summary

Summary

The main goal of this RCT is to verifying the therapeutic effects of skin allograf in compare with silver sulfadiazine ointment in deep second degree burn injuries of trunk and limbs. Fifty patients randomly divided in 2 groups(each one 25 patients)with inclusion criteria which were: deep second degree burn injuries in trunk and limbs, BSA between 10 to 20 percent, age above 18 and less than 65 years old without any comorbidities. We excluded patient with old burning, infected wounds, other medical conditions and candidates for autograft skin grafts. In intervention group we applied skin allografts produced by ITP company(Iranian tissue products) as a biological bandage; in control group we used silver sulfadiazine ointment. The rate of infection was measured by culture from wounds if the patients had symptoms like fever or leucocytosis.The pain was measured with the scale called VAS and also the amount of IV pain killer consumption mentioned in questionare.and the scar and epitelialisation evaluated in days 7,14 and 30.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112431074N1**
Registration date: **2017-02-13, 1395/11/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-13, 1395/11/25

Registrant information

Name

Ali Farahanchi Baradaran

Name of organization / entity

Zanjan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of dressing with skin allograft and silver sulfadiazine in deep second degree burn wounds in Zanjan Ayatollah Mousavi hospital, 2016-2017

Public title

Therapeutic effect of skin allograft in deep second degree burn wounds

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: patients with thermal deep second degree burn wound who are admitted in our ward, age

above 18,with out respiratory burning, with out any comorbidities like addiction. History of DM, renal disease, malignancies, psychiatric problems and non- pregnant patients. Exclusion criteria: head and neck burn wounds; genitalia burn wounds; pregnant patients; third and forth degree burn wounds; unstable patients; patients with burn wounds BSA>20% or BSA<10%; psychiatric patients; addict and smoker patients; patients with other comorbidities like renal and hepatic problem, DM, malnutrition and immunocompromised patients, respiratory burning, old wounds; infected wounds and age below 18.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zanjan University of Medical Sciences

Street address
Zanjan University of Medical Sciences, Azadi blvd.

City
Zanjan

Postal code

Approval date
2016-11-23, 1395/09/03

Ethics committee reference number
IR.ZUMS.REC.1395.204

Health conditions studied

1

Description of health condition studied
Deep second degree burn wounds of limbs and trunk

ICD-10 code
T21.2

ICD-10 code description
Burn of second degree of trunk

Primary outcomes

1

Description
Pain

Timepoint
Daily during admission

Method of measurement
VAS scale

2

Description
Epitelialisation duration

Timepoint
days: 7, 14 and 30

Method of measurement
Physical examination

3

Description
Amount of IV pain killer

Timepoint
Daily during admission

Method of measurement
Nursing report

4

Description
Finall remaining scar

Timepoint
Day 30 after intervention

Method of measurement
Physical examination and questionare

Secondary outcomes

1

Description
Addmision days

Timepoint
Time of discharge

Method of measurement
Discharge ward

2

Description
Number of bandage refreshment

Timepoint
Daily during admission

Method of measurement
Nursing report and direct checking

3

Description
Treatment cost
Timepoint
At the time of discharge
Method of measurement
Finall bill

4

Description
Infection
Timepoint
During admission
Method of measurement
Culture from wound

Intervention groups

1

Description
In control group we used silver sulfadiazine ointment daily after washing the wounds.we consume 20 gram of ointment for each percent of burn wound(each tube is consist of 50 gram of ointment).
Category
Treatment - Drugs

2

Description
In intervention group we applied skin allografts produced by ITP company(Iranian tissue products) as a biological bandage.first we sutured the allograft with few simple stiches then with we badage with wet gauze (under anestesia in OR)the day after procidure we remove the bandage and dry it by heat lamp and do not bandage any more.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi hospital
Full name of responsible person
Dr. Mohammad Hossein Moghimi
Street address
Burn ward, Ayatollah Mousavi hospital , Gavazang road
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Ali Reza Shoghli
Street address
Zanjan University of Medical Sciences, Azadi blvd.
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Ali Farahanchi Baradaran
Position
MD, resident of surgery
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Surgery, Zanjan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hosein Moghimi
Position

Assistant professor of general surgery
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty