

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 questionnaire.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

Iran (Islamic Republic of)

Phone

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Email address

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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 anesthesia 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

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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