

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between effect of Alpha and Silver Sulfadiazine ointments in treatment of burned patients

Protocol summary

Summary

The purpose of this study is comparison between effect of Alpha and Silver Sulfadiazine ointments in treatment of burned patients. In this study we compare difference of wound healing, scar formation, infection, pain scale, analgesic receipt and days of hospitalization in patient who are treated with Alpha and Silver Sulfadiazine ointments. Our study is a prospective study which is a Randomized Clinical Trial. This study was done on 20 patient with two upper or two lower limb burning, where in each patient; one limb dressed with Alpha ointment and the other limb was dressed with Silver Sulfadiazine ointment. Patients with inclusion criteria which was second degree burning and burning surface between 10% to 20% enter to this study. In these patient we choose the patients who had two burned limb. Some patients exclude from study by exclusion criteria which was old burning and other medical diseases. In all, 20 patient with 40 burned limb was studied. We dressed all wounds once a day with 20 milligrams of each ointment for every 1% of burning wound. In the first and 7th and 14th day of burning we got cultures from wounds swaps, and in the 7th and 14th and 30th day we evaluate the healing of wounds through photogeraphy and objective evaluation. In 30th day of burning we evaluate scar of wounds in the patients for compare between Alpha and Silver Sulfadiazine ointments wounds. Patients' pain scale was assessed with Visual Analog Scale (VAS) in first fourteen days of admit. And use or do not use of pethidine analgesia in first fourteen days of admit was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110624905N1**

Registration date: **2016-02-09, 1394/11/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

Name

Payman Sadri

Name of organization / entity

Zanjan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 24 3342 0651

Email address

sadrip@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2014-09-27, 1393/07/05

Expected recruitment end date

2015-03-16, 1393/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between effect of Alpha and Silver Sulfadiazine ointments in treatment of burned patients

Public title

The effect of alpha ointment in treatment of burned patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Second degree heat burned patients; burning surface area between 10% and 20% Exclusion criteria: isolated head and neck burning; burning of genitalia; pregnant women; first and third and fourth degree burning; unstable patients; burning surface area above 20% or under 10%; patients with history of neurocystic diseases who are under treatment; addiction to opioids; smokers; patients with history of cardiac, renal or hepatic diseases; diabetic patients; malnourished patients; patients under treatment of corticosteroids or other immune suppressive treatments; inhalative burnings; sulfonamide toxicity; old burnings

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Science

Street address

Central office of Zanjan University of Medical Science,
Azadi Blvd, Zanjan, Iran

City

Zanjan

Postal code

Approval date

2014-09-14, 1393/06/23

Ethics committee reference number

ZUMS.REC1393.199

Health conditions studied

1

Description of health condition studied

Burning

ICD-10 code

X10; X11;

ICD-10 code description

Contact with hot drinks, food, fats and cooking oils;

Contact with hot tap-water; Contact with other hot fluids

Primary outcomes

1

Description

Rate of ulcer healing

Timepoint

Seventh, 14th, 30th day

Method of measurement

Evaluation of patient in the admission time and evaluation of ulcers in 7th and 14th day of admission and out patient in day 30th. In every visit photography of ulcers was done.

2

Description

The rate of scar

Timepoint

Thirtieth day

Method of measurement

Two other colleagues who were not aware of our protocol, visited patients in 30th day and scored rate of scar in 4 qualitative scale item like excellent, good, intermediate, poor. And the remaining scar was reported in percentage.

3

Description

The rate of positive culture

Timepoint

First, 7th, 14th day

Method of measurement

The culture of wound swab in the first, 7th and 14th day of admission.

Secondary outcomes

1

Description

The rate of patients' pain

Timepoint

Daily

Method of measurement

VAS (visual analogue scale) in first 14 day

2

Description

Dose of recieved analgesia

Timepoint

Daily

Method of measurement

Evaluation of pethidine consumption in firs 14 day

3

Description

Days of admission

Timepoint

Daily

Method of measurement

Questionnaire

Intervention groups

1

Description

Patients in the burning ward, was treated accidentally with Alpha ointment which made in Rejoderm company and Silver Sulfadiazine ointment which made in Sina Darou company. In this study we choose patients with two burned limbs and if they were compatible with our criterias, the intervention was done in two separate limbs where one limb dressed with Alpha and the other limb was dressed with Silver Sulfadiazine. Dressing of wounds was done daily after washing of the wounds with sterile Normal Saline serum. Every one percent of wounds was macerated with twenty Gram of Alpha or Silver Sulfadiazine ointment. We used vaseline gauzes to cover the Alpha ointment dressings and sterile gauzes to cover the Silver Sulfadiazine dressings. Then these dressings was fixed with cotton bands. Dressing of wounds was continued until epithelialization of whole wounds.

Category

Treatment - Drugs

2

Description

Because this study was done over patients with two burned limbs, in all patients one limb accidentally was dressed with Alpha ointment and the other limb was dressed with Silver Sulfadiazine ointment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital, Zanjan

Full name of responsible person

Payman Sadri

Street address

Ayatollah Mousavi Hospita, Ganazang road, Zanjan,

Iran

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Science

Full name of responsible person

Payman Sadri

Street address

Ayatollah Mousavi Hospital, Gavazang road, Zanjan, Iran

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 Science

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 Science

Full name of responsible person

Payman Sadri

Position

General Surgeon

Other areas of specialty/work

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Web page address

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