

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of sesame oil and topical silver sulfadiazine 1% on improving the extent of burn and epithelialization of patients with second degree burn

Protocol summary

Summary

The aim of this study is to compare the topical application of sesame oil and silver sulfadiazine 1% in the treatment of patients with second degree burns. Inclusion criteria: All patients hospitalized with second degree burns in burn ward of Nekoi Hospital of Qom. Exclusion criteria: Age less than 2 years, comorbid diseases, inhalation burns, third degree burns and burn over 25% of body surface. In this trial, 60 patients are randomly assigned into two groups. Then in case group topical sesame oil (Made by Merck company of Germany) is used and control group will receive silver sulfadiazine 1% ointment (Made by Sina Daroo Company with trade name of Flamexin). The application is so that silver sulfadiazine or sesame oil will be used without any additive and will be placed and covered by a sheet of cellophane on burn wound. The dosage of sesame oil or sulfadiazine is determined based on the extent of the lesion and will be used once a day until recovery. The extent of reduction burns, the need for analgesic and antibiotic compounds, the extent of residual scarring and recovery time in both groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201188769N1**
Registration date: **2012-09-19, 1391/06/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-09-19, 1391/06/29

Registrant information

Name

Seyed Jalal Eshagh Hosseini

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25171181

Email address

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of sesame oil and topical silver sulfadiazine 1% on improving the extent of burn and epithelialization of patients with second degree burn

Public title

Sesame oil and silver sulfadiazine in second degree burn

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients hospitalized with second degree burns in the burn center of Nekoi Hospital of Qom
Exclusion criteria: Age less than 2 years, comorbidity

with diseases, inhalation burns, third degree burns, burns over 25% of body surface

Age

From **2 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This is a single blind study. Patients are not informed of the drugs used after obtaining informed consent. Randomization is based on a predefined random numbers table so that even numbers will be assigned to participate in case group and odd numbers will be in the control group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Lavasani St., Qom

City

Qom

Postal code

Approval date

2011-10-02, 1390/07/10

Ethics committee reference number

34/12078/پ

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

The extent of burn

Timepoint

Before the intervention and every three days until epithelialization

Method of measurement

Ruler and extent based on square centimeters

Secondary outcomes

1

Description

The need for antibiotic

Timepoint

Every day until discharge

Method of measurement

Number of doses

2

Description

The need for analgesic drugs

Timepoint

Every day until discharge

Method of measurement

Number of doses

3

Description

The extent of residual scar

Timepoint

Weekly after the intervention until one month after full recovery

Method of measurement

Ruler and extent based on square centimeters

Intervention groups

1

Description

For the patients in control group topical Silver sulfadiazine 1% ointment (Made by Sina Daroo company of Iran, with trade name of Flamexin) is used once a day. The dosage is determined based on the extent of the lesion

Category

Treatment - Drugs

2

Description

For the patients in case group pure topical sesame oil

(Made by Merk company of Germany) is used once a day.
The dosage is determined based on the extent of the lesion

Category

Treatment - Other

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

Nekoi Hospital

Full name of responsible person

Seyed Jalal Eshagh Hosseini, MD.

Street address

Nekoi Hospital, Azar St., Qom

City

Qom

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Education, Research and Technology of Qom University of Medical Sciences

Full name of responsible person

Ali-Reza Koochpayee

Street address

Qom University of Medical Sciences, Vice chancellor for Education, Research and Technology, Lavasani St., Qom

City

Qom

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for Education, Research and Technology of Qom 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**

Qom University of Medical Sciences

Full name of responsible person

Seyed Jalal Eshagh Hosseini, MD.

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Surgeon, Assistant professor

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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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