

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the effect of sesame oil and 1% silver sulfadiazine ointment on the pain, healing and scarring of burn wounds

Protocol summary

Study aim

Comparison of the effect of sesame oil and 1% silver sulfadiazine ointment on the pain, healing and scarring of burn wounds

Design

Clinical trial, double-blind with parallel groups, randomized, in phase 3, 40 patients will be selected as available and allocated by permutation blocks method.

Settings and conduct

The place of intervention was the emergency department of Bohloul hospital. For the sesame oil group, first, the wound area will be washed with sodium chloride and exposed to the open air for 5 minutes until it dries completely. Then, the wound area is smeared with 2 ml of sesame oil (for 10 square centimeters of the wound) and the surface of the wound is covered with freezer plastic and then it will be bandaged. For the silver ointment group, all the above steps have been done and the wound will be dressed with 1% silversulfadiazine ointment. At the end, the diagnosis of wound healing will be confirmed by a specialist. The emergency medicine physician and the data analyst will be unaware of the patient grouping.

Participants/Inclusion and exclusion criteria

Informed consent to participate in the study Age 20-60 years First and second degree burns with an extent of 1-10% Burns due to contact with a heat source or liquids Less than 6 hours passed from the time of the burn to the time of going to the treatment center Hemoglobin and total protein normal Absence of underlying diseases such as anemia, diabetes, cardiovascular diseases, malignancy and immune system deficiency Not taking painkillers and NSAIDs orally or topically until the first visit to the treatment center Confirmation by the doctor that the patient does not need to be hospitalized Not allergic to sesame oil

Intervention groups

Dressing group with sesame oil, will be dressed with sesame oil. Dressing group with 1% silver sulfadiazine

ointment, will be dressed with silver ointment.

Main outcome variables

Healing & scars

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180221038821N5**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Iman Ghorbany Moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 0576

Email address

ghorbani.i@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of sesame oil and 1% silver sulfadiazine ointment on the pain, healing and scarring of burn wounds

Public title
Comparison of the effect of sesame oil and 1% silver sulfadiazine ointment on the pain, healing and scarring of burn wounds

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Informed consent to participate in the study Age 20-60 years First and second degree burns with an extent of 1-10% Burns due to contact with a heat source or liquids
Exclusion criteria:
 Sesame oil allergy Confirmation of the need for hospitalization of the patient by the doctor Taking painkillers and NSAIDs orally or topically until the first visit to the treatment center Background diseases such as anemia, diabetes, cardiovascular diseases, malignancy and immune system defects Abnormal hemoglobin and total protein More than 6 hours passed from the time of the burn to the time of going to the medical center

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were first selected by the available method and then divided into two groups of sesame oil and silver ointment by using 4 permutation blocks. In this method, the sesame oil group was coded with the letter A and the silver ointment group was coded with the letter B. The six possible states in the blocks included ABAB, BBAA, AABB, BABA, AAAA, BBBB, and each block was assigned a number. For every four selected people, a number will be selected according to the list, and people will be assigned to two groups of sesame oil and silver ointment in this way.

Blinding (investigator's opinion)
Double blinded

Blinding description
The emergency medicine doctor who will confirm the recovery of the patients will not know about the grouping of the patients. The data analyst will also be unaware of

the grouping of patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethnical Committee of Gonabad University of Medical Sciences
Street address
 Asian Road Rim, Gonabad University of Medical Sciences
City
 Gonabad
Province
 Razavi Khorasan
Postal code
 96916-47161
Approval date
 2022-12-24, 1401/10/03
Ethics committee reference number
 IR.GMU.REC.1401.137

Health conditions studied

1

Description of health condition studied
Burn

ICD-10 code
Z73.0

ICD-10 code description
Burn-out

Primary outcomes

1

Description
Wound healing time

Timepoint
After confirming the healing of the wound by an emergency medicine specialist

Method of measurement
Questionnaire (Day)

2

Description
The scar left by the wound

Timepoint
After confirming the healing of the wound by an

emergency medicine specialist
Method of measurement
Beitz-Johnson Burn Wound Assessment Tool

Secondary outcomes

1

Description

Intensity of pain

Timepoint

Before and after dressing in the first session

Method of measurement

Visual pain scale

Intervention groups

1

Description

Intervention group: Sesame oil group: For the sesame oil group, the burn wound dressing with sesame oil will first be washed with sodium chloride for washing and exposed to the open air for 5 minutes until it dries completely. Then, the wound area is smeared with 2 ml of sesame oil (for 10 square centimeters of the wound) and the surface of the wound is covered with freezer plastic (to absorb more sesame oil) and then it will be bandaged. Sesame oil used in this notice will be completely natural and without preservatives with standard devices from a local store and will be prepared under supervision. It should be noted that this extract is 100% oily and in addition to being free of water molecules, it also contains antimicrobial compounds that prevent the growth of microbial agents in this extract. Nevertheless, in order to ensure the negativity of the microbial culture, random samples of the extract prepared in the microbial culture media of blood agar, chocolate agar, eosin methylene blue, Kant agar plate, lauryl sulfate broth and selected culture media for the investigation of yeasts and fungi will be used.

Category

Treatment - Drugs

2

Description

Intervention group: Silversulfadiazine 1% group: Dressing the burn wound first, the wound area will be washed with normal saline for washing and exposed to the open air for 5 minutes until it dries completely. Then the wound will be smeared with 1% silver sulfadiazine ointment and covered with freezer plastic and bandaged. One percent silver sulfadiazine ointment of Iran Najo Pharmaceutical Company will also be used for this group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlol Hospital, Gonabadi

Full name of responsible person

Dr. Mehdi Pasban

Street address

Parastar Blvd

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 0576

Email

info@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Mansourian

Street address

Asian Roads, Gonabad University of Medical Sciences, Student Research Committee

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 0576

Email

info@gmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Iman Ghorbany Moghaddam

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No9, Behesht Street, Emam Sajjad Blvd, Gonabad Town

City

Gonabad

Province

Razavi Khorasan

Postal code

9691647161

Phone

+98 51 5722 0576

Fax**Email**

imanghorbany135213@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Moosa Sajjadi

Position

Head of the Center for the Study and Development of Medical Sciences Education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Asian Roads, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 0576

Email

sajjadi1975@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Iman Ghorbany Moghaddam

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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imanghorbany135213@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available