

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of herbal ointment with silver sulfadiazine ointment on second degree burn wounds

Protocol summary

Study aim

Evaluation of the effect of herbal ointment with silversulfadiazine ointment on second-degree burn injuries in patients referred to emergency department of Motahari Hospital in Tehran in 2019,20

Design

A double-blind clinical trial with parallel groups including treatment groups with herbal ointment and silver sulfadiazine ointment, randomizing by randomizer software and sample size of 54 cases including 27 cases in each groups

Settings and conduct

The statistical population of this study is patients with second-degree burns referring to Motahari hospital in Tehran, who are over 18 years of age and have criteria for entering the study. A thin layer of herbal ointment or silver sulfadiazine ointment based on randomization of patients, and without informing the patients about the contents of the ointment cans, is applied to their burn wounds. Patients are required to come back to the hospital for dressing change, evaluation of wounds and assessing for possible complications. Before each dressing change, the wounds are evaluated and digital images are taken from the wounds. In the group receiving herbal ointment, intervention is continued until the end of the fourth week, but in the group receiving silver sulfadiazine ointment, the base of the herbal ointment is used to continue the intervention from start of third week until the end of the fourth week.

Participants/Inclusion and exclusion criteria

Second degree heat burn; age over 18 years; Less than 48 hours from the burns happening; Burn percentage less than 15%; Patient's informed consent to participate in the research project.

Intervention groups

group 1: Wound dressing with a thin layer of herbal ointment daily until complete wound healing group 2: Wound dressing with a thin layer of silver sulfadiazin 1% ointment daily until complete wound healing

Main outcome variables

wound healing time, wound size changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190621043961N1**

Registration date: **2019-10-03, 1398/07/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-03, 1398/07/11**

Update count: **0**

Registration date

2019-10-03, 1398/07/11

Registrant information

Name

Mehdi Alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4601 6943

Email address

m_alizadeh@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of herbal ointment with silver sulfadiazine ointment on second degree burn wounds

Public title

The effect of herbal ointment on second degree burn wound

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

second degree burn wound age over 18 years less than 48 hours from the onset of burn injury Burn percentage less than 15% Informed consent to participation in research

Exclusion criteria:

Pregnant women Patients with severe systemic diseases such as epilepsy, diabetes, immune deficiency History of psychotic disorder such as paranoid; history of admission to psychiatry department Patients with a history of skin allergies to the components of the product Electrical and chemical burns Unwillingness to continue the intervention Allergy to Silver Sulfadiazine or Ointment Co-administration of antibiotics (oral and topical)

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **57**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of the samples is done by Randomizer software in a simple random way for patients with inclusion criteria. With using Randomizer software, sequential numbers randomly divided into two groups of intervention and control. Then patients referred to the intervention or control group will be placed in the same order. For patients with two burn areas, each area from the right to the left (conventionally) is considered a number.

Blinding (investigator's opinion)

Single blinded

Blinding description

Dressing change of the patients is done daily in the hospital and the patients do not know the type of prescribed ointment and also because before each dressing, wounds are washed and clean by the patients at home, the assessor also do not aware of the type of wound treatment group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-03-03, 1397/12/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1330

Health conditions studied**1****Description of health condition studied**

second degree burn wound

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes**1****Description**

recovery of burn wound

Timepoint

At first and the fourth day, then at the end of the first, second, third and fourth weeks

Method of measurement

photography and slide-calliper

Secondary outcomes**1****Description**

general wound appearance

Timepoint

days 1, 4, 7 and at the end of second, third and fourth

weeks
Method of measurement
observation

2

Description
Pain
Timepoint
daily
Method of measurement
VAS scale

3

Description
itching
Timepoint
daily
Method of measurement
Visual analog scale

4

Description
inflammation
Timepoint
daily
Method of measurement
observastion

5

Description
percentage of wound contraction
Timepoint
days 1, 4, 7 and at the end of second, third and fourth weeks
Method of measurement
photography and calliper

6

Description
infection
Timepoint
daily
Method of measurement
observation

7

Description
redness
Timepoint
daily
Method of measurement
observation

Intervention groups

1

Description
Intervention group: wound dressing with a thin layer of herbal ointment daily until the end of one month after the start of intervention.

Category
Treatment - Drugs

2

Description
Control group: wound dressing change with a thin layer of silver sulfadiazine 1% ointment daily until complete wound healing and then until the end of a month after the onset of intervention, the base of ointment replaces the silversulfadiazine ointment.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital

Full name of responsible person

Mehdi Alizadeh

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Rashid Yasemi Ave., Kordestan Blvd., Tehran, Iran

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146651194

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hospital.motahari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehdi Alizadeh

Position

MD, PhD Candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publishing results in form of a PhD thesis and an article indexing in ISI

When the data will become available and for how long

after PhD thesis defence

To whom data/document is available

Public

Under which criteria data/document could be used

for research reasons

From where data/document is obtainable

Shahid Beheshti University of Medical Sciences

What processes are involved for a request to access

data/document

approving by responsible officer

Comments