Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
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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

inflamation

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