

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of the effect of wound dressing with chamomile cream 10% and silver sulfadiazine 1% cream on healing time and complications of two degree burn wounds

Protocol summary

Study aim

Determination and comparison of second degree burn time and burn injuries in two methods of dressing with chamomile cream and silver sulfadiazine cream

Design

Samples will be randomly assigned to two groups of 30, and each group was dressed daily with a type of cream (chamomile or silver sulfadiazine 1%) until complete wound healing. The duration of recovery and burn complications in the two groups will be measured and compared

Settings and conduct

Outpatients referring to Imam Mousa Kazem Medical Center Clinic in Isfahan will be studied if they have entry criteria.

Participants/Inclusion and exclusion criteria

The age range from 18 to 60 years old, has a second degree burn with an area of 10-1% and no underlying disease

Intervention groups

Chamomile group: Chamomile cream dressing up to full recovery and silver group: Silver sulfadiazine cream dressing until complete recovery.

Main outcome variables

Duration of restoration, complications of burn wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180424039406N1**

Registration date: **2018-09-19, 1397/06/28**

Registration timing: **retrospective**

Last update: **2018-09-19, 1397/06/28**

Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Mahdi Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

daryabeigi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-22, 1397/01/02

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-03-22, 1397/01/02

Trial completion date

2018-03-22, 1397/01/02

Scientific title

Comparison of the effect of wound dressing with chamomile cream 10% and silver sulfadiazine 1% cream on healing time and complications of two degree burn wounds

Public title

Comparison of the effect of wound dressing with chamomile cream 10% and silver sulfadiazine 1% cream on healing time and complications of two degree burn wounds

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. One person is between 18 and 60 years old
2. Individuals are only exposed to hot liquids or heat sources.
3. Persons with grade 2 burns according to the criteria Class 2 burns with a wound burn of between 1% and 10%
The ulcer of the patients is not infected and has not been injured. People did not use any substance other than drinking water for wound healing before going to the clinic. The burn wounds are not located in the head and face areas of the genital area, and only in the trunk and limbs (hands and feet). Substance Abuse (Alcohol, Drugs) The body mass index is between 18.5 and 30. People without underlying illness Women not included in the study are pregnant.

Exclusion criteria:

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Actual sample size reached: **67**

Randomization (investigator's opinion)

Randomized

Randomization description

After making the cards A and B (with the same size), they were placed inside a non-transparent envelope and the sample group is determined based on the card removed from the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Use the cream with a uniform and uniform A or B package

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical

Sciences

Street address

Isfahan University of Medical Sciences, Assistant Professor of Research and Technology, University of Medical Sciences

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-12-22, 1396/10/01

Ethics committee reference number

IR.MUI.REC.1396.3.701

Health conditions studied

1

Description of health condition studied

Burn of second degree

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

The duration of wound healing

Timepoint

Daily wound examination until definite symptoms of complete recovery

Method of measurement

See symptoms of complete wound healing by a researcher

Secondary outcomes

1

Description

Side effects when taking any of the ointments, such as sensitivity, burning and infections

Timepoint

Every day when changing dressings

Method of measurement

By observing the wound by the researcher and verifying it by a specialist physician

2

Description

pain

Timepoint

daily

Method of measurement

Using the VAS ruler

Intervention groups

1

Description

Intervention group: Dressing with chamomile cream 10% (made at Isfahan Pharmaceutical Faculty), which is changed daily until wound healing is approved by the checklist.(The base of the cream is similar to the other group).

Category

Treatment - Drugs

2

Description

Control group: Daily dressing with 1% silver sulfadiazine cream (Produced by Sobhan Darou), which is changed daily until wound healing is approved by the checklist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Imam Musa Kazem (AS) burn injury center in Isfahan

Full name of responsible person

Mahdi Ebrahimi

Street address

Isfahan, Kaveh St. - Imam Musa Kazem (AS) burn injury center in Isfahan

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medk45v@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mahdi Ebrahimi

Position

Masters student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Reza Daryabigi

Position

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Latest degree

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Person responsible for updating data

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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