

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Adding Combination of honey and butter to Silver Sulfadiazine on Healing Time and Infection Rate in Second-degree Burning: Randomized Controlled Clinical Trial

Protocol summary

Study aim

Study of the combination of honey and butter on time of care and infection rate of second-degree burning

Design

Randomized clinical trial with control group, Parallel groups, double blinded, sample size is 70

Settings and conduct

The study will be conducted in Maragheh and Tabriz hospitals. The ointments are packaged in completely similar packages as ointment A and B, and patients are randomly assigned to receive supplements. The patient will use ointment for dressing burn area with the same type of ointment. In addition to nurse care, every 3-4 days the patient will be examined by another researcher for the presence of burn infection and the rate of recovery. Patients, medical staff, and statistical analyzer are not aware of medications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Heat burn; Second-degree Burn; Wound area below 10%. Non-inclusion criteria: burn occurred more than 6 hours; Age under 12 years old; burns grade 1 or grade 3 and above; Chronic diseases such as cancer or diabetes

Intervention groups

Intervention group: will receive standard treatment plus honey and butter ointment. Control group: Only receive standard burn treatment that includes silver sulfadiazine ointment.

Main outcome variables

Burn healing time; Infection status; Burn scar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120112008712N4**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **prospective**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Mojtaba Ziaee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2021-01-31, 1399/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Adding Combination of honey and butter to Silver Sulfadiazine on Healing Time and Infection Rate in Second-degree Burning: Randomized Controlled Clinical Trial

Public title

Honey and butter in treatment of burning

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

2nd Degree Burning Heat Burning Burning area under 10%

Exclusion criteria:

Over 6 hours of burning time Age under 12 years old 1st degree burning or higher than 2nd degree Hypersensitivity to dairy compounds, or combinations of drugs or dressing; Comorbidity. Pregnancy or breastfeeding People under chemotherapy or immunosuppressive drugs Hemoglobin and total protein are less than normal. The patient's wound is impregnated with contaminating material. Burn in the facial, hands and genital areas Diabetic Patients

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **35**

2 groups: Honey and Butter combination versus only Silver Sulfadiazine Groups

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to intervention and control groups based on permissive block design. First, a single-digit random number will be generated if the chosen number is 0 to 4 AB permutation will be used and if it is between 5 and 9 BA permutation will be used. This method will be employed to complete the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

All Patients, nurses, and doctors, as well as statistical analyzers, will be unaware of the treatment codes

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mojtaba Ziaee

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Approval date

2018-03-15, 1396/12/24

Ethics committee reference number

IR.MARAGHEHPHC.REC.1397.003

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

Burn of second degree

ICD-10 code

T29.2

ICD-10 code description

Burns of multiple regions, no more than second-degree burns mentioned

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

Percentage of burn wounds area

Timepoint

Area of wound at the beginning of the study (before the intervention) and on 3, 7 and 14 days, and then every 15 days until complete recovery

Method of measurement

Using a digital camera, the shot will be taken from the pre-dressing stage from 15 cm distance, and the area of the wound will be estimated using the AutoCAD software from the wound images.

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

Infection

Timepoint

Third, Seventh, Fourteenth and completed healing days

Method of measurement

microbial culture

Intervention groups

1

Description

In the intervention group: Before examining the wound, patients will be examined by a physician, based on a checklist. After washing and drying the burned tissue, kefir ointment and 10% extract of *Malva sylvestris* is applied to the wound area. Silver sulfadiazine 1% ointment is then applied and the wound will be dressed. In this study, wound healing would be evaluated on days 1, 3, 7 and 14 after-burn.

Category

Treatment - Drugs

2

Description

In the control group: Before examining the wound, patients are examined by a physician based on a standard checklist. Then the limb or the burned area is washed with normal saline and dried by sterile gas. Silver sulfadiazine 1% ointment would be applied with sterile gloves on the wound. In this study, wound healing would be evaluated on days 1, 3, 7 and 14 after-burn.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Gholamreza Farid Alaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maragheh University of Medical Sciences

Full name of responsible person

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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

Maragheh 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

Maragheh University of Medical Sciences

Full name of responsible person

Gholamreza Farid alaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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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