Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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
Street address
North Moallem St., Maragheh, East Azerbaijan, Iran
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Maragheh
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Postal code
5518578151
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
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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
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Position
Associate professor
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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