

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

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

Protocol summary

Study aim

Study of combination of Kefir and Malva Sylvestris 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 new kefir and Malva sylvestris 10% 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: **IRCT20120112008712N3**

Registration date: **2019-10-31, 1398/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

Registration date

2019-10-31, 1398/08/09

Registrant information

Name

Mojtaba Ziaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3725 6920

Email address

ziaee.m@srbiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-01, 1398/07/09

Expected recruitment end date

2020-08-01, 1399/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Kefir and Malva sylvestris 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 Chemical or Electrical Burning Hypersensitivity to milk 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 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: Kefir and Malva sylvestris combination versus only Silver Sulfadiazine Groups

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization with computer software

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

Ethics committee of Maragheh University of Medical

Sciences

Street address

North Moallem St., Maragheh, East Azerbaijan, Iran

City

Maragheh

Province

East Azarbaijan

Postal code

5518578151

Approval date

2019-06-13, 1398/03/23

Ethics committee reference number

IR.MARAGHEHPHC.REC.1398.011

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

2

Description

wound Scare

Timepoint

Third, Seventh, Fourteenth and completed healing days

Method of measurement

Digital Photography

Intervention groups

1

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

2

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

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Gholamreza Farid Alaei

Street address

North Moallem St., Maragheh, East Azerbaijan, Iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maragheh University of Medical Sciences

Full name of responsible person

Gholamreza Farid Alaei

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North Mollem

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5515878151

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ghf.alaaei@yahoo.com

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 alaaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Maragheh University of Medical Sciences

Full name of responsible person

Mojtaba Ziaee

Position

assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

There is not more information

When the data will become available and for how long

.

To whom data/document is available

.

Under which criteria data/document could be used

.

From where data/document is obtainable

.

What processes are involved for a request to access data/document

.

Comments

.

Person responsible for updating data**Contact****Name of organization / entity**

Maragheh University of Medical Sciences

Full name of responsible person

Mojtaba Ziaee

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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