Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the healing effects of a natural oint based on herbal oil, honey and egg yolk on 1st and 2nd degree burn wounds

Protocol summary

Study aim
Determining the healing effects of natural oint based on herbal oil, honey and egg yolk on first and second degree burn wounds

Design
Clinical trial with control group, single, double blind, randomized, phase 1-2, on 70 patients. The rand function of Excel software is used for randomization

Settings and conduct
The wounds of patients referred to Kausar Sanandaj Hospital are divided into two equal parts in terms of the largest dimension. Burn ointment based on vegetable oil is applied on one side and usual treatment is done on the other side. Simple masking gas is used for the control level and gauze impregnated with burn ointment is used for the intervention level. Care is similar.At the beginning of the study and also after two days and 5 days of using the effective substance, the two criteria of the level of disinfection and the level of healing of the wound are evaluated by an expert.

Participants/Inclusion and exclusion criteria
Exclusion criteria:3rd degree burns, patients' dissatisfaction in participating in the plan ,death of patients, stopping treatment in patients whose wound healing process is problematic; Inclusion criteria:1st and 2nd degree burn patients referred to Kausar Sanandaj Hospital

Intervention groups
Intervention group:Treatment with burn ointment (based on natural oils, honey and eggs), which is performed on the left side in horizontal wounds, upper side in vertical wounds, and right side in oblique wounds.Gauze impregnated with burn ointment is used at the intervention site.Control group: usual clinical procedures are performed on the right side in horizontal wounds, the bottom in vertical wounds and the left side in oblique wounds. A simple masking gas is used for the control surface.

Main outcome variables
Surgical Site Infection; Early Healing Score which includes clinical signs of re-epithelization, clinical signs of haemostasis, clinical signs of inflammation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141208020249N8**
Registration date: **2024-09-23, 1403/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-23, 1403/07/02**
Update count: **0**

Registration date
2024-09-23, 1403/07/02

Registrant information
Name
Behzad Khalafi
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
2024-08-22, 1403/06/01

Expected recruitment end date
2025-08-23, 1404/06/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the healing effects of a natural oint based on herbal oil, honey and egg yolk on 1st and 2nd degree burn wounds

Public title

Investigating the healing effects of a natural oint based on herbal oil, honey and egg yolk on 1st and 2nd degree burn wounds

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1st and 2nd degree burn patients referred to Kowsar Sanandaj Hospital who consent to participate in the research project.

Exclusion criteria:

Dissatisfaction of patients in participating in the study Death of patients Stopping treatment in patients who have problems with wound healing

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **2**

In order to randomly assign the type of treatment, wounds are divided into two equal parts, and A, which is a burn ointment based on vegetable oils, honey and eggs, is divided into the left parts in horizontal wounds, the top in vertical wounds and The right side is allocated in oblique wounds and the other side is treated B.) usual clinical procedures are performed.

Randomization (investigator's opinion)

Randomized

Randomization description

We divide the burn site into two parts (half medial) A and (half lateral) B and use the drug under study as follows. The part of the burn that does not receive the study drug will be partially controlled. 0001: A 0007: B 0013: B 0019: A 0025: A 0031: B 0002: B 0008: A 0014: A 0020: B 0026: B 0032: B 0003: A 0009: B 0015: B 0021: B 0027: B 0033: B 0004: A 0010: B 0016: A 0022: B 0028: B 0034: A 0005: A 0011: A 0017: A 0023: B 0029: A 0035: B 0006: A 0012: A 0018: A 0024: A 0030: A

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double-blind, so that the doctor responsible for measuring the outcome/intervention and the patient will be blind to the type of intervention received.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Abider Street

City

Sanandaj

Province

Kurdistan

Postal code

6618634683

Approval date

2024-06-19, 1403/03/30

Ethics committee reference number

IR.MUK.REC.1403.070

Health conditions studied

1

Description of health condition studied

1st and 2nd degree burns

ICD-10 code

T30

ICD-10 code description

Burn and corrosion, body region unspecified

Primary outcomes

1

Description

Surgical Site Infection score

Timepoint

Before starting the study and 2 and 5 days after the intervention

Method of measurement

In this measure, Surgical Site Infection (SSI) indicators based on CDC guidelines are used to evaluate the risk of wound infection.

2

Description
Early Healing Score
Timepoint
Before starting the study and 2 and 5 days after the intervention
Method of measurement
EHS evaluation consists of clinical signs of re-epithelization (CSR), clinical signs of haemostasis (CSH) and clinical signs of inflammation (CSI).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Treatment with burn ointment (based on natural oils, honey and eggs), which is performed on the left side in horizontal wounds, upper side in vertical wounds, and right side in oblique wounds.Gauze impregnated with burn ointment is used at the intervention site
Category
Treatment - Drugs

2

Description
Control group: The usual clinical procedures (mefenaid ointment) are performed on the right side in horizontal wounds, the bottom in vertical wounds and the left side in oblique wounds. (The wound is divided into two equal parts in terms of the largest dimension). It is used for the control surface.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Sanandaj Hospital
Full name of responsible person
Behzad Khalafi
Street address
Kawsar Hospital, Shohadaye Salamat Blvd, Pasdaran St.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Sanandaj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Sanandaj University of Medical Sciences
Full name of responsible person
Behzad Khalafi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All the original data will be published in the form of an article, and supplementary data can be obtained from the responsible author upon reasonable request.

When the data will become available and for how long
2025 spring

To whom data/document is available
Official academic researchers or working in commercial research and development units

Under which criteria data/document could be used
Scientific research uses

From where data/document is obtainable
Researchers can request documents or data files by sending an email to the person responsible for the scientific responsibility of the study. The exact response time is not known. The email address and details of the person responsible for responding are as follows: The full name of the responsible person: Behzad Khalafi Email: khalafi.behzad70@gmail.com Phone +98 87 3377 7925 Address: Pasdaran Street, Shahada Salamat Blvd., Kawsar Hospital Postal code 6617784817

What processes are involved for a request to access data/document
First, the researchers send an e-mail to the person responsible for the scientific response(The full name of the responsible person: Behzad Khalafi Email: khalafi.behzad70@gmail.com) and specify which of the data they want. The information (except for the personal information of the participants) will be available to the said person after reviewing the request through e-mail.

Comments