Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Assessing the effect of Olea ointment (a compound of honey, olive, and sesame) on infection and granulation tissue formation in second degree burn wounds - A randomized clinical trial

Protocol summary

Summary

Objectives: This study aimed to investigate the effect of Olea ointment (topical honey ointment) in preventing infection and speeding up the formation of granulation tissue in the second degree burn. Design: 30 patients who had second degree burns (burn depth of 0.2 to 5.0 mm) were investigated as the study population. Setting and conduct: This was a randomized controlled trial which was conducted in the burn ward in Tohid hospital in Sanandaj. The patients were divided into two groups using simple randomized method (using computer); the chance of entering the control group was twice as that of the intervention group. Thus 20 patients were allocated in the control group and 10 patients were allocated in the intervention group. Participants and inclusion and exclusion criteria: According to inclusion criteria people with second degree burns and with burns equal or less than 40% of body surface area were enrolled in the study. Patients with underlying conditions such as diabetes, chronic renal or hepatic diseases, and patients with burns and concomitant trauma, and with concomitant skin tears were excluded. Interventions: One of the groups was treated on a daily basis using topical Olea ointment (FaraTeb Co, Iran) and the other group using Acetate Mafenide ointment (8.5%, Sina Daru, Iran). Main outcome variables: Wound infection and granulation tissue formation were considered as the main outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020516490N1**
Registration date: **2014-04-11, 1393/01/22**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-04-11, 1393/01/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2005-10-23, 1384/08/01

Expected recruitment end date

2006-12-22, 1385/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of Olea ointment (a compound of honey, olive, and sesame) on infection and granulation tissue formation in second degree burn wounds - A randomized clinical trial

Public title

Effect of Olea ointment on burn wounds

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who had second degree burns (burn depth of 0.2 to 5.0 mm); burns covered 40% or less of their body surface area; were aged between 15 to 40 years; consented to participate in the study; referred at the first 24 hours of injury; and had negative ulcer culture on admission. Exclusion criteria: patients with underlying conditions such as diabetes; chronic renal or hepatic diseases, and patients with simultaneous burns, trauma, and skin lacerations.

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

Vice chancellor for research, Medicine School, Pasdaran Ave

City

Sanandaj

Postal code

6617713446

Approval date

2005-09-23, 1384/07/01

Ethics committee reference number

1384/42/پ

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T22.2

ICD-10 code description

Burn of second degree of shoulder and upper limb, except wrist and hand

Primary outcomes

1

Description

Wound infection

Timepoint

A week after intervention

Method of measurement

Culture

Secondary outcomes

1

Description

Situation of granulation tissues formation

Timepoint

A week after intervention

Method of measurement

Pathology

Intervention groups

1

Description

Intervention group 1 was consisted of 10 patients who were treated using Olea ointment (manufactured in Farateb Co. Iran). Olea ointment contains 33.4% honey, 33.3% olive oil and 33.3% Sesame oil. After washing the wound with normal saline solution, 3-5 mm of Olea ointment was applied over the wound and closed dressing was performed every day.

Category

Treatment - Drugs

2

Description

The intervention group 2 was consisted of 20 patients; they were treated using 1-2 mm thick of Acetate Mafenide ointment (8.5%, manufactured by Sina Daro pharmaceutical company, Iran) over the wound.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tohid Hospital
Full name of responsible person
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Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kurdistan University of Medical Sciences
Full name of responsible person
Dr Ataollah Heidari
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Grant name
HSR طرح پژوهشی غیر
Grant code / Reference number
1384/42
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kurdistan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty