Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Investigating the healing effects of topical spray containing effective herbal ingredients on burn wounds of patients with grade 1 and 2 burn wound

Protocol summary

Study aim
Investigating the healing effects of topical spray containing effective herbal ingredients on burn wounds of patients with grade 1 and 2 burn wound

Design
A controlled, triple-blind, randomized, phase 3 clinical trial on 40 patients. To randomize the patients, the random block method with a block size of four is used

Settings and conduct
The study will be conducted on burn patients referred to Hamadan (Iran) hospitals. Placebo and herbal formulation will be prepared by researcher in two similar containers. The herbal formulation container will be labeled as X and the the placebo container will be labeled as Y and only the researcher is aware of the container's contents. Neither the participant nor the clinician nor the statistical analyst know about the contents of the labeled containers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients (men and women) from the age of 10 to 70 years with 2nd and 3rd degree burns involving least 1 cm 2 of their body surface area. Exclusion criteria: hypersensitivity to herbal formulations; have a history of asthma or chronic obstructive pulmonary diseases; patients with diabetic ulcers; patients with skin lesions.

Intervention groups
The first group, test 1: in this group, the burn wounds will be treated with silver sulfadiazine cream in the morning and 12 hours later the wounds will be treated with herbal spray, the second group, test 2: the burn wounds will be treated with herbal spray every 12 hours, the third group, the positive control group: the burn wounds will be treated with silver sulfadiazine every 12 hours and the fourth group, the placebo control group: the wounds will be treated with SSD every morning and12 hours later with placebo.

Main outcome variables
Faster and more effective healing of burn wound by herbal formulation compared to placebo

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240221061068N1**
Registration date: **2024-02-29, 1402/12/10**
Registration timing: **prospective**

Last update: **2024-02-29, 1402/12/10**
Update count: **0**

Registration date
2024-02-29, 1402/12/10

Registrant information
Name
Pari Tamri
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
2024-05-21, 1403/03/01
Expected recruitment end date
2024-12-21, 1403/10/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the healing effects of topical spray containing effective herbal ingredients on burn wounds of patients with grade 1 and 2 burn wound

Public title
Evaluation of the effects of a topical spray containing effective herbal ingredients on burn wound
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age group 10 to 70 years Having first and second degree burns involving at least 1 cm2 of body area surface Full consciousness so that she/he is able to understand the instructions and take care of herself (including not rubbing, touching and scratching the burn site)
Exclusion criteria:
Hypersensitivity to herbal spray formulation having a history of asthma, COPD, hay fever, rhinitis and skin sensitivity Having a skin lesion that prevents the evaluation of the burn wound. ق‌eceiving anti-inflammatory drugs(eg, glucocorticosteroids and NSAIDs) Concurrent participation in another clinical trial to investigate an agent affecting burns
Age
From **10 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize the patients, the random block method with a block size of four is used. For this purpose, four sheets of paper are prepared. The letter T (test) is written on two sheets and the letter C (control) is written on the other two sheets. The sheets are mixed together and placed in a box. With each eligible patient's visit, one of the sheets is randomly drawn and based on whether the drawn sheet is T or C, it is assigned to one of the two test or control groups. It should be noted that the drawn cards are not returned to the box until all four cards have been drawn. After all four sheets are randomly drawn, all sheets are returned to the corresponding box and the above operation is continued for the next four patients until the desired sample size is reached. The method of blinding herbal formulation and placebo is prepared by the researcher and prepared in a spray container and provided to the doctor and shift nurse. The container containing the solution of active herbal ingredients are marked as X and the bottles containing the placebo are marked as Y, and only the researcher is aware of the contents of the spray bottles, the examining doctor and nurse, the patient himself and The statistical analyst does not know any of the content inside the labeled container
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd
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Postal code
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Approval date
2024-02-17, 1402/11/28
Ethics committee reference number
IR.UMSHA.REC.1402.718

Health conditions studied

1

Description of health condition studied
Second and third- degree burns
ICD-10 code
T20-T25
ICD-10 code description
Burns and corrosions of external body surface, specified by site

Primary outcomes

1

Description
Burn wound healing percentage
Timepoint
The wound area of all participant will be calculated every 24 hours during study.
Method of measurement

To calculate the wounds areas, photographs will be taken of the wounds and the area of each wound will be calculated using ImageJ image analysis software.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1, will be treated with SSD in the morning and with herbal formulation 12 hours later,
Category
Treatment - Drugs

2

Description
Intervention group 2: will be treated with the herbal formulation twice a day.
Category
Treatment - Drugs

3

Description
Intervention group: will be treated with SSD twice a day.
Category
Treatment - Drugs

4

Description
Control group: will be treated with SSD in the morning and with placebo 12 hours later."
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Be'sat hospital
Full name of responsible person
Mehdi Eskandarloo
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Hokama St., Shahid Motahri Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Pari Tamri
Position
Assistant professor
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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

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