Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Assessing therapeutic effects of a topical ointment containing the extract of Arnebia euchroma and amniotic membrane in patients with burn; a randomized controlled trial

Protocol summary

Study aim
Determining the therapeutic effect of ointment containing Arnebia euchroma extract and amniotic membrane in patients with burn wounds

Design
patients with 1st or 2nd degree burn wounds are divided into two groups. Patients in both groups receive standard treatment for burn wounds. One group apply Abu Khalsa ointment and the other group apply silver sulfadiazine every 24 hours for 14 days. Wound healing is investigated by determining its extent and the time required for wound healing in the Abu Khalsa ointment group is compared with the silver sulfadiazine group. Statistical t and chi square tests will be used to compare the effects of herbal medicine and silver sulfadiazine on the important parameters of days of recovery after treatment, wound size, edema, hematoma, itching, pain, and infection.

Settings and conduct
Patients rub the medicine on the wounds every 24 hours for 14 days. The study is conducted in Razi Hospital. On the can of medicines, a label with the title 1 or 2 is placed, and the patient and other people are unaware of the meaning of the numbers on the label.

Participants/Inclusion and exclusion criteria
Entry criteria - Age 18 to 60 years - Second degree burns - The extent of wound between 1 and 10% - Less than 6 hours should pass from the occurrence of the burn to the time the patient goes to the treatment center - The location of the wound is on the limbs and trunk Non-entry criteria - Suffering from underlying diseases - Taking drugs that weaken the immune system - The patient's unwillingness to continue participating in the research

Intervention groups
intervention group apply Arnebia euchroma ointment and the control group apply silver sulfadiazine every 24 hours for 14 days on the wounds.

Main outcome variables
the time required to heal the wound; wound size; human; hematoma; itching; pain; infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181005041243N4**
Registration date: **2024-07-08, 1403/04/18**
Registration timing: **prospective**

Last update: **2024-07-08, 1403/04/18**
Update count: **0**

Registration date
2024-07-08, 1403/04/18

Registrant information

Name
Nika Kianfar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2285 7201

Email address
N-kianfar@alumnus.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-01, 1403/06/11

Expected recruitment end date
2025-09-02, 1404/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing therapeutic effects of a topical ointment containing the extract of Arnebia euchroma and amniotic membrane in patients with burn; a randomized controlled trial

Public title

Therapeutic effect of ointment containing extract of Arbenia Euchromia plant and amniotic membrane in burn wound

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 18-60 Burns due to contact with hot liquids or heat sources, patients with second degree burns according to the criteria determined according to the reference sources as follows: 1. The surface of the burn is red or pink in color. 2- It has a moist surface with liquid oozing or accompanied by blisters. 3- Having extreme sensitivity when touching The extent of the burn wound is between 1 and 10%, which is determined based on the criteria of Lund and Browder Less than 6 hours should pass from the occurrence of the burn to the time the patient goes to the treatment center The patient's wound was free of infection and trauma The wound of the patient should be only on the limbs and trunk and not in the head, face and genital area.

Exclusion criteria:

Suffering from diseases such as anemia, diabetes, malignancies and immune system defects due to the impact on the wound healing process. Taking drugs that weaken the immune system and are effective on wound healing, such as steroid drugs - substance abuse The patient's unwillingness to continue participating in the research or not returning to the treatment center Damage to the burn wound during the intervention, chemotherapy or radiation therapy during the research and showing signs of sensitivity to 1% silver sulfadiazine or the study drug during the intervention pregnancy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of individuals to groups is done in the form of random allocation in blocks of four. In this way, first the volume of each block is specified (block of four), then the list of blocks is specified with the help of www.randomizer.org and numbers are assigned to them (numbers 1 to 15 for 60 people) and each of the numbers with the list of treatment specific to you is placed in an envelope. Then, the people included in the research randomly select envelopes containing numbers between 1 and 15, and the allocation of people to two groups 1 and 2 is determined based on the list of four blocks of each number.

Blinding (investigator's opinion)

Single blinded

Blinding description

A label is placed on the can containing the drug and 1% silver sulfadiazine. The number 1 or 2 is written on the sticker of the can containing medicine (extract) and the number 1 or 2 is written on the label of the can containing 1% silver sulfadiazine. Other specifications included on the said labels are completely the same. The patient and other people are unaware of the nature and meaning of the numbers 1 and 2 on the label. The place of blinding is in the research institute.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Ghods St., Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1936893813

Approval date

2024-06-26, 1403/04/06

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.135

Health conditions studied

1

Description of health condition studied

Burn wound

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determining the extent of the wound and the time required to heal the wound
Timepoint
At the beginning of the study (before the start of the intervention) and 14 days after starting to use ointments
Method of measurement
The size of the wound is determined by a ruler and the time required to heal the wound is determined by a doctor's visit.

Secondary outcomes

1

Description
edema; hematoma; itching; pain; infection
Timepoint
At the beginning of the study (before the start of the intervention) and 14 days after starting to use ointments
Method of measurement
doctor's opinion

Intervention groups

1

Description
Intervention group: Ointment name: Arnebia euchroma, chemical composition and its concentration: extracts are prepared by soaking plant materials in (67%-EtOH) under ultrasound at room temperature. The extracts will be filtered through Whatman No. 1 filter paper, and then the filtrates were successively combined and concentrated under vacuum by a rotary evaporator. Then, in a special mill, the dry extract will be mixed with the oily base composition and it will be kept for 73 hours in a special tank in the dark at a temperature of 37 degrees Celsius. The final product is sterilized by gamma radiation (23 kg). Dosage: In both groups, after washing the burn wound with 0.9% sterile saline solution, the wound is placed in the vicinity of the open air for 5 minutes until its surface is completely dry, then using a sterile water hose to complete the measurements. The surface of the burn wound should be covered with a thickness of 3 mm, ointment number 1 or 2 is applied to the wound, and a layer of sterile gauze is placed on the wound. Wound dressings are changed daily for up to 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr. Maryam Nasimi
Street address
Razi Hospital, Vahdate eslami St.
City
Tehran
Province
Tehran
Postal code
11996 6391
Phone
+98 21 5563 0553
Email
nsm.maryam@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Reza Ghafarzadegan
Street address
Medicinal Plants Research Institute, Jihad Academic Research Complex, Behesht Sakineh St., Karaj-Qazvin freeway
City
Tehran
Province
Tehran
Postal code
131451446
Phone
+98 26 3476 4010
Email
sec.imp@acecr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranian academic center for education culture and research
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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Maryam Nasimi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
General Practitioner

Street address
Razi Hospital, Vahdate eslami St.

City
Tehran

Province
Tehran

Postal code
11996 63911

Phone
+98 21 5563 0553

Email
nsm.maryam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Maryam Nasimi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
General Practitioner

Street address
Razi Hospital, Vahdate eslami St.

City
Tehran

Province
Tehran

Postal code
11996 63911

Phone
+98 21 5563 0553

Email
nsm.maryam@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Maryam Nasimi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
General Practitioner

Street address
Razi Hospital, Vahdate eslami St.

City
Tehran

Province
Tehran

Postal code
11996 63911

Phone
+98 21 5563 0553

Email
nsm.maryam@gmail.com

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
Yes - There is a plan to make this available

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

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Part of the data, such as the information related to the main outcome, can be shared. All information will be published in the form of a work report and finally a scientific article. If you need all the data, it is possible for the person in charge of the plan to provide the information without patients being identifiable.

When the data will become available and for how long
The access period starts immediately after the results are printed

To whom data/document is available
Only researchers working in academic and scientific institutions

Under which criteria data/document could be used
The data will only be given to researchers who are researching the same topic.

From where data/document is obtainable
Responsible for the project: Dr. Maryam Nasimi Address: Razi Hospital, Vahdat Eslami St. Number: 09128435986 Email: nsm.maryam@gmail.com

What processes are involved for a request to access data/document
After sending a reasonable request to the person in charge of the project by email, if the conditions are met, the information will be shared with them.

Comments