Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Clinical evaluation of common mallow extract on the second degree burn wounds

Protocol summary

Study aim
Clinical evaluation of the effect of cream containing common mallow extract on burn wound healing in patients referred to Taleghani Hospital in Ahvaz

Design
Clinical trial of phase 2-3 with control and intervention groups, with parallel groups, double blind, randomized

Settings and conduct
This study will be performed as a randomized clinical trial on patients with second degree burns with an area of 5-50% referred to Taleghani Burn Hospital in Ahvaz. Patients will receive routine daily treatment. These patients will be randomly divided into two groups who will randomly receive a placebo or herbal ointment. Unique codes provided by the software will be used on medicine boxes. In this study, data collection method is used to determine the duration of wound healing by observing the wound by a physician and completing a questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 5-60 years, burns due to contact with heat source or liquids, Less than 2 hours have passed from the time of burn to the time of hospitalization. Exclusion criteria: Underlying diseases such as anemia, diabetes, cardiovascular disease, malignancy, immune deficiency, cytotoxic drugs and allergic disease

Intervention groups
Patients are randomly divided into two groups of treatment and control. The test and control group will use herbal ointment or placebo on the wound once a day for 15 days.

Main outcome variables
Determining the mean Bets-Jensen wound evaluation score of patients with second degree burns in the first, seventh, fifteenth days in the control and control groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200128046288N4**
Registration date: **2020-10-27, 1399/08/06**
Registration timing: **prospective**

Last update: **2020-10-27, 1399/08/06**
Update count: **0**

Registration date
2020-10-27, 1399/08/06

Registrant information

Name
Fereshteh Golfakhrabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3373 8378

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golfakhrabadi-f@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Clinical evaluation of common mallow extract on the second degree burn wounds

Public title
Evaluation of effect of common mallow on the burn wounds
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 5-60 years Burns due to contact with heat source or liquids Less than 6 hours have passed from the time of burn to the time of hospitalization Normal hemoglobin and total protein levels of patients
Exclusion criteria:
Underlying diseases Such as anemia, diabetes, cardiovascular disease, malignancy, immune deficiency, cytotoxic drugs and allergic disease, Allergy to common mallow
Age
From **5 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method is used Blocking is used to balance the number of samples assigned to each study group, because we have two intervention groups, use equal 4 blocks and create all 4 possible modes and then with Excel software we randomly select a number of blocks. The label of interventions to one of the letters A or B and the sequence of randomization determined by the statistical consultant. For allocation concealment, drug delivery and the sequence of randomization is not available to researchers and evaluators while is the responsibility of the off-site individual.
Blinding (investigator's opinion)
Double blinded
Blinding description
Unique codes, which is generated by the software, will be used on the drug and placebo boxes. By entering each individual into the study based on the produced sequence, the drug or placebo box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences,, Golestan street
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2020-10-19, 1399/07/28
Ethics committee reference number
IR.AJUMS.REC.1399.569

Health conditions studied

1

Description of health condition studied
second degree burns
ICD-10 code
T21.2
ICD-10 code description
Burn of second degree of trunk

Primary outcomes

1

Description
Wound size
Timepoint
The first day of the burn, the seventh day and the fifteenth day
Method of measurement
With shooting and ruler

2

Description
Comparison of burn wound healing
Timepoint
The first day of the burn, the seventh day and the fifteenth day
Method of measurement
Based on the standard Bets Jensen numerical questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Herbal cream once a day for 15 days
Category
Treatment - Drugs

2

Description
Control group: Placebo cream once a day for 15 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani hospital in Ahvaz
Full name of responsible person
Abdolreza Sheikhi
Street address
In front of police station 23, Phase 2 of Padadshahr, Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadi Moghaddam
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Ahvaz Jundishapur University of Medical Sciences, Golestan street
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Fereshteh golfakhrabadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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
Yes - There is 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
Only part of the data will be shared
When the data will become available and for how long
The access time is up to 6 months after the results are published
To whom data/document is available
Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.
Under which criteria data/document could be used
Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.
From where data/document is obtainable
Applicants can email the responsible author to receive the requested data golfakhrabadi@yahoo.com
What processes are involved for a request to access data/document
Applicants will have access to the data from the present study by emailing the responsible author for up to one month. golfakhrabadi@yahoo.com
Comments