

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)

Phone

+98 61 3373 8378

Email address

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

Khuzestan

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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6187954386

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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

Street address

Ahvaz Jundishapur University of Medical Sciences,
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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 scientific inquiries

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Email

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