Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

: The effect of oral Calendula officinalis on the wound healing in second degree burn

Protocol summary

Summary

Objective:care/ wound healing.Design of the study:randomized,double blind,controlled,single-centered,stage two trials.study population:patients with burn.Entrance criteria:have second degree burn.Exit criteria:Unwillingness to continue to study.Sample size:60 Intervention or interventions After receiving a letter of intent and posting a questionnaire, the intervention group will receive, in addition to the usual treatments, for 2 weeks, once a day, a capsule containing 2 grams of flower extract and the capsule control group containing the placebo. The wound condition is examined using the Bets-Jensen standard on the first, seventh and fifth days of the study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070334880N1**
Registration date: **2017-09-20, 1396/06/29**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2017-09-20, 1396/06/29

Registrant information

Name

SORAYA REZAEE

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 864173638

Email address

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Recruitment status

Not enough for processing

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2017-05-10, 1396/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: The effect of oral Calendula officinalis on the wound healing in second degree burn

Public title

- The effect of Calendula officinalis on second-degree burns-

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Second degree burns; Burn percentage between 15 and 50% (based on Landau Browder chart); The samples should be between the ages of 18 and 55 years; Over 48 hours of burn injury; In the burn area, be hospitalized; Do not be fast; Participate in the study; Not pregnant; Do not breastfeed; Lack of underlying diseases such as diabetes, cancer, or infectious diseases; Do not abuse substance (alcohol, narcotics, and sedation). Exclusion criteria: Unwillingness to continue to study; Release of patient; Transfer to another department; Patient's death

Age

From **18 years** old to **55 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Use the blocking technique

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street
City
Arak
Postal code
3848176941
Approval date
2017-05-22, 1396/03/01
Ethics committee reference number
IR.ARAKMU.REC.1396.44

Health conditions studied

1

Description of health condition studied
second degree burn
ICD-10 code
T30.2
ICD-10 code description
Burn of second degree, body region unspecified

Primary outcomes

1

Description
wound healing
Timepoint
In the days of 1,7 and 15
Method of measurement
BATES-JENSEN WOUND ASSESSMENT TOOL

Secondary outcomes

1

Description
Burn percentage
Timepoint
In the days of 1,7 and 15
Method of measurement
Landau Brothers Chart

2

Description
Burn depth
Timepoint
In the days of 1,7 and 15
Method of measurement
BATES-JENSEN WOUND ASSESSMENT TOOL

Intervention groups

1

Description
Intervention group 1: Calendula, capsule of 500 mg orally, twice daily for fourteen days
Category
Placebo

2

Description
Control group: Starch,A capsule of 500 mg orally, twice daily for fourteen days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
soraya rezai
Street address
Valiasr Hospital Vali Asr Square arak iran
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mojtaba Bagheri
Street address
Sardasht,Arak University of Medical Sciences
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

Contact
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SORAYA REZAEE
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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