Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Oral Centella Asiatica on pain and wound healing of burns

Protocol summary

Study aim

determine the effect of Edible centella asiatica on pain and wound healing of burns

Design

A randomized, double blind, placebo-controlled clinical trial of 76 samples.

Settings and conduct

After getting the letter of satisfaction and filling the questionnaire, intervention group's members, in addition to usual treatment, take twice 250 mg capsule containing juice of centella Asiatica daily twice for two weeks and the control group like intervention group takes placebo capsule. Wound situation is measured with Bates –jensen tool, on the firs day ,seventh day and eleventh day. The pain situation will be also measured daily with VAS tool .

Participants/Inclusion and exclusion criteria

Inclusion criteria : second grade burning sore ;the percentage of burning between 15 to 55 (according to lund-browder chart); the age range of the samples should be between 18 - 55 ;at the most after 48 hours of burning ; the cases should be hospitalized in burn section ; No fasting; should be volunteer of presence in the study .Exclusion criteria : Prgnancy; Lactation ; being affected to underlying diseases like :infectious ,diabetes , cancer, and hypertension; drugs addiction; mental disorders; allergy

Intervention groups

In this work, the intervention group received cream-colored capsule containing 250 mg of centella asiatica , prepared by the Karaj Drug Research Unit, twice daily for 2 weeks, and the control group also received a cream-colored capsule containing 250 mg of starch twice daily For 2 weeks, they will receive the same kind of capsules in the drug research unit of Karaj Jahad University

Main outcome variables

Pain; wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181229042166N1**
Registration date: **2019-04-06, 1398/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-06, 1398/01/17**
Update count: **0**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Robabeh Kazemi Dermanaki Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3324 7899

Email address

r.kazemidermanaki@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-09, 1397/11/20

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Oral Centella Asiatica on pain and wound

healing of burns

Public title
Effect of centella asiatica on pain and wound healing of burns
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
second degree burn Burn percent 15-55% (according to Land Browder chart) volunteer of presence to study Hospitalized in burn section 15-55 age limits at the most after 48 hours of burning No fasting
Exclusion criteria:
Unwillingness to participate in the study Pregnancy being affected to underlying diseases like diabetes ,cancer, infectious diseases, hypertension Drug Addiction Allergy psychosis disorder Lactation
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Ranomized block design and selection of 6th and 8th blocks.Individual randomization unit.for randomise , first for random allocation ,Random sequence created with use of ''random allocation soft ware ''and then based on volume sample that is 76,76 envelopes with aluminium cover were provided and each of random Sequence were registered on a card and placed in the envelope orderly. for keeping random Sequence on orderthe outer surface of envelopes ,numbering is performed in the same way .the envelopes are Pasted and placed orderly inside the box and Based on the entry of participants to the study ,on of the envelopes are opened.then that participant 's allocated group is revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to eliminate the bias caused by the patient or physician's knowledge of the type of treatment received and its possible effect on the outcome of the study, the study is done Double blind . Due to the fact that the centella Asiatica and placebo capsules are placed in the same full capsule, it is natural that the patient and the person evaluating the received medication are unaware.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
Arak Medical Sciences University,Rah Ahan Ave.,Allamalhoda st.,
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2018-10-21, 1397/07/29
Ethics committee reference number
IR.ARAKmu.REC.1397.186

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
pain
Timepoint
Daily. For two weeks after the intervention began
Method of measurement
VAS TOOL(Visual analogue scale)

2

Description
Wound healing
Timepoint
Before the intervention and one and two weeks after the intervention began
Method of measurement
Bates -Jensen wound Assessment Tool

Secondary outcomes

1

Description
Burn percentage
Timepoint
Before the intervention and two weeks after the intervention
Method of measurement
Landdbrooder chart

Intervention groups

1

Description
The intervention group will receive two capsules250 mg centella asiatica ; prepared by the Medicines Department of Karaj Jahad University; for two weeks.
Category
Treatment - Other

2

Description
Control group will received two 250 mg starch capsules; prepared by the Medicines Department of Karaj Jahad University; daily for two weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Robabeh Kazemi Dermanaki Farahani
Street address
Valiasr Hospital,Valiasr Sq., Arak, IRAN
City
AraK
Province
Markazi
Postal code
3816986658
Phone
+98 86 3324 7899
Email
bahar.kazemi38@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Mohammad Arjmandzadegan
Street address
Arak University of Medical Sciences - Basij Sq., Arak
City
Arak
Province
Markazi
Postal code
٣٨١٩٦٩٣٣٤٥
Phone
+98 86 3313 6055
Fax
+98 86 3313 3147
Email
mmatinam81@yahoo.com
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
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
Arak University of Medical Sciences
Full name of responsible person
Robabeh Kazemi Dermanaki Farahani
Position
Senior student is discontinuous
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No.1,Ettehad Alley.,Etteha Ave., Barekat Square.,Hmid Town Hamid Town
City
Arak
Province
Markazi
Postal code
3816986658
Phone
+98 86 3324 7899
Fax
Email

r.kazemidermanaki@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Kobra Rahzani

Position
Ph.D. in Nursing

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Arak University of Medical Sciences, Sardasht Sq.

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3417 3524

Email
k.rahzani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Robabeh Kazemi Dermanaki Farahani

Position
Senior student is discontinuous

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No.1,Ettehad Alley.,Etteha Ave., Barekat Square.,Hmid Town

City
Arak

Province
Markazi

Postal code
3816986658

Phone
+98 86 3324 7899

Fax

Email
r.kazemidermanaki@arakmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not 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
Not applicable