

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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 first 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

Landbrooder chart

Intervention groups

1

Description

The intervention group will receive two capsules 250 mg centella asiatica ; prepared by the Medicines Department of Karaj Jihad 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 Jihad 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

۳۸۱۹۶۹۳۳۴۰

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

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