

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of inhalation aromatherapy with lavender extract on pain and anxiety in burn patients: a randomized clinical trial

Protocol summary

Summary

Patients who have Inclusion criteria were as simple random sampling are selected, so that the 120 paper, a color, a shape that the 40 by the letter A and 40 letters B and 40 letter C written so that their letters be covered. Each of the participants in an envelope at random and without replacement will choose and thus in one of the groups A, B, and C will be. About half an hour before dressing, visual analogue scale of pain intensity in patients with burns self to be checked. Then for half an hour intervention is done so that the groups inhalation aromatherapy, intervention in this case would be the principal investigator of 10 drops of essential oil of Astkhdvs in Group A and 10 drops of distilled water in Group B with dropper on gas attached to clothing or pillows participation and group C will receive treatment and routine care. Also the number of housing request by any of the subjects to be checked 12 hours after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030632129N3**

Registration date: **2017-05-17, 1396/02/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-17, 1396/02/27

Registrant information

Name

Azim Azizi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

a.azizi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inhalation aromatherapy with lavender extract on pain and anxiety in burn patients: a randomized clinical trial

Public title

Extracts of lavender on pain and anxiety in patients with burns

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: degree burns 2, alertness naturally able to speak clearly, confirmed the doctor's lack of a ban on entry to the study, lack of sensitivity to herbal medicines, non-drug addiction (based on patient testimony), lack of brain tumor, stroke head, epilepsy, lack of mental disorders, there is no problem of smell, lack of focus pain of others, the use of perfume by the

patient simultaneously, burns 30% of body surface area based on the criteria Lund and Browder, 48 hours of patient past the hospital, the fire does not burn because, aged 18 to 55 years. Exclusion criteria: Use of herbal medicines by the patients, creating any disturbance of smell, causing respiratory problems and allergic withdraw from the study at any stage of the study, participated in a similar study at the same time (aromatherapy), based on the scale, visual analogue pain less than 3, less patient anxiety score of 20 on a scale of Der Burger.

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: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamedan University of Medical Sciences

Street address

Hamadan University of Medical Science, Shahid Fahmide boulevard, Hamadan

City

Hamadan

Postal code

00988138380150

Approval date

2017-03-05, 1395/12/15

Ethics committee reference number

IR.UMSHA.REC.1395.591

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T20-T25

ICD-10 code description

Burns and corrosions of external body surface

Primary outcomes

1

Description

pain

Timepoint

3 times in 3 days

Method of measurement

pain Chart

2

Description

Anxiety

Timepoint

3 times in 3 days

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The scent of lavender is used in the intervention group

Category

Treatment - Other

2

Description

The scent of lavender is used in the intervention group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Atefe lashani

Street address

Hamadan, Babak Crossroads, Besat hospital

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of
Hamadan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

Street address

Hamadan University of Medical Science, Shahid
Fahmide boulevard, Hamadan

City

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technology of
Hamadan 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**Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Azim Azizi

Position

PhD in Nursing

Other areas of specialty/work**Street address**

Hamadan University of Medical Science, Shahid
Fahmide boulevard

City

Hamadan

Postal code

00988138380150

Phone

+98 81 3838 0150

Fax**Email**

a.azizi@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamadan University of Medical Science

Full name of responsible person

Azim Azizi

Position

PhD in nursing

Other areas of specialty/work**Street address**

Hamadan University of Medical Science, Shahid
Fahmide boulevard

City

Hamadan

Postal code

00988138380150

Phone

+98 81 3838 0150

Fax**Email**

a.azizi@umsh.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity****Full name of responsible person****Position****Other areas of specialty/work****Street address****City****Postal code**

00988138380150

Phone

+98 81 3838 0150

Fax**Email**

a.azizi@umsh.ac.ir

Web page address

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