

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Investigation on the effectiveness inhalation aromatherapy with Lavender essential oil versus placebo on the anxiety of patients with burns. a double blinded randomized clinical trial

Protocol summary

Summary

Objective: effects of inhalation aromatherapy with Lavender essential oil on the anxiety of patients with burns. Design: Double blinded randomized clinical trial. Setting and conduct: the patients with following criteria will be enrolled into the study; age 18 to 65 years; b) burns degree of 2 or 2 and 3 and with 15 to 60 percent burn level; c) lack of inhalation burns; d) lack of allergy or respiratory diseases; e) lack of narcotic addiction or drug abuse. Exclusion criteria included: Lack of patient cooperation during the intervention for any reason; creation dangerous condition of disease during the intervention; allergy to inhalation of Lavender essential oil during the intervention. Intervention 1: in the first night, anxiety of patients will be controlled. Then, for 20 minutes patients inhale 2 drops of Lavender essential oil 2% produced by Hyrad Company which was poured onto 10×10 cm gauze attached to collar of patients' shirt. The anxiety of the patients will be controlled again 20 minutes later. Intervention 2: in the first night, anxiety of patients will be controlled. Then, for 20 minutes patients inhale 2 drops of distilled water as placebo which was poured onto 10×10 cm gauze attached to collar of patients' shirt. The anxiety of the patients will be controlled again 20 minutes later. In the second and third night, the intervention will be implemented in the same way. Main outcome measures: Anxiety will be measured by Spielberger questionnaire.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2013042413110N1**
Registration date: **2015-06-27, 1394/04/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-27, 1394/04/06

Registrant information

Name

Mehdi Harorani

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on the effectiveness inhalation aromatherapy with Lavender essential oil versus placebo on the anxiety of patients with burns. a double blinded randomized clinical trial

Public title

Investigation on the effectiveness inhalation aromatherapy with Lavender essential oil versus placebo on the anxiety of patients with burns. a double blinded randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 65 years; burns degree of 2 or 2 and 3 with 15 to 60 percent burn level; stability of hemodynamic status; lack of inhalation burns; lack of allergy or respiratory diseases; lack of narcotic addiction or drug abuse. Exclusion criteria: Lack of patient cooperation during the intervention for any reason; creation dangerous conditions of disease during the intervention; allergy to inhalation of Lavender Essential Oil during the intervention.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City

Arak

Postal code

38481-76941

Approval date

2015-04-20, 1394/01/31

Ethics committee reference number

p/2/94c6276

Health conditions studied

1

Description of health condition studied

Burns

ICD-10 code

T31.2, T31

ICD-10 code description

Burns involving 20-29% of body surface, Burns involving 30-39% of body surface, Burns involving 40-49% of body surface, Burns involving 50-59% of body surface, Burns involving 60-69% of body surface

2

Description of health condition studied

Anxiety

ICD-10 code

F38

ICD-10 code description

Any other mood disorders that do not justify classification to F30-F34, because they are not of sufficient severity or duration

Primary outcomes

1

Description

Anxiety

Timepoint

Before and 20 minutes after inhalation of lavender (experimental group) or distilled water (control group) for three consecutive nights

Method of measurement

Spielberger questionnaire

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

the patients for 20 minutes inhale 2 drops of Lavender essential oil 2% produced by Hyrad Company which was poured on to 10×10 cm gauze attached to collar of patients' shirt. The anxiety of the patients will be controlled again 20 minutes later. In the second and third night, the intervention will be implemented in the same way.

Category

Treatment - Drugs

2**Description**

for 20 minutes patients inhale 2 drops of distilled water as placebo which was poured on to 10×10 cm gauze attached to collar of patients' shirt. The anxiety of the patients will be controlled again 20 minutes later. In the second and third night, the intervention will be implemented in the same way.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital Arak

Full name of responsible person

Mehdi Harorani

Street address

Arak, Valiasr Hospital

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-Chancellor of Education and Research Arak
University of Medical Sciences

Full name of responsible person

Dr. Ali Ghazavi

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City

Arak

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor of Education and Research 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University Of Medical Sciences

Full name of responsible person

Mehdi Harorani

Position

Master of Science in Nursing

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

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Full name of responsible person

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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