Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mehdi Harorani
Name of organization / entity
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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
Arak

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
Street address
Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak
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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
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Person responsible for updating data

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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