Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of inhalation aromatherapy with Damask Rose (Rose Damascena) essential oil versus placebo on the pain and vital signs in the burn patients after dressing: a single blinded randomized clinical trial

Protocol summary

Summary

Objective: effects of inhalation aromatherapy with Rose Damascene essential oil on pain and vital signs in the patients with burns after dressing. Design: single blinded randomized clinical trial. Setting and conduct: the patients with following criteria will be enrolled into the study; a) age18 to 65 years; b) burns degree of 2 or 2 and 3 and with 15 to 45 percent burn level; c) lack of electrical or inhalation burns; d) lack of allergy or respiratory diseases; e) lack of narcotic addiction or drug abuse. Exclusion criteria included: a) Lack of patient cooperation during the intervention for any reason; b) creation dangerous condition of disease during the intervention; c) allergy to inhalation of Damask Rose essential oil during the intervention. Intervention1: in the first day, the base line of the vital signs and the pain of patients will be controlled in half an hour before entering into the dressing room and the patients inhale 5 drops of Damask Rose (Rose Damascene) essential oil 40% produced by Hyrad Company which was poured onto 10×10 cm gauze attached to collar of patients' shirt and then will go to dressing room. The pain and vital signs of the patients will be controlled in minutes of 15 and 30 after exiting of dressing room. Intervention2: in the first day, the base line of the vital signs and the pain of patients will be controlled in half an hour before entering into the dressing room and the patients inhale 5 drops of distilled water as placebo which was poured onto 10×10 cm gauze attached to collar of patients' shirt and then will go to dressing room. The pain and vital signs of the patients will be controlled in minutes of 15 and 30 after exiting of dressing room. In the second day, in the both interventions, mentioned works will be conducted in the similar way again. Main outcome measures: Pain will be measured by Pain Visual Analog Scale and Vital signs will be measured manually and by blood pressure monometer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302249759N4**
Registration date: **2013-07-29, 1392/05/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-29, 1392/05/07

Registrant information

Name

Ali Bikmoradi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0439

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of inhalation aromatherapy with Damask Rose (Rose Damascena) essential oil versus placebo on the pain and vital signs in the burn patients after dressing: a single blinded randomized clinical trial

Public title
The effect of inhalation aromatherapy with Damask Rose on the pain and vital signs in the patients with burn

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: a) age18 to 65 years؛ b) burns degree of 2 or 2 and 3 with 15 to 45 percent burn level; c) stability of hemodynamic status; d) lack of electrical or inhalation burns; e) lack of allergy or respiratory diseases; f) lack of narcotic addiction or drug abuse. Exclusion criteria: a) Lack of patient cooperation during the intervention for any reason; b) creation dangerous conditions of disease during the intervention; c) allergy to inhalation of Damask Rose essential oil during the intervention.

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

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Sampling is conventional and eligible patients to enter the study will be allocated by lottery to experiment and control groups gradually.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Postal code
6517838698

Approval date
2013-05-02, 1392/02/12

Ethics committee reference number
287/9/35/16/p/d

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

2

Description of health condition studied
Pain in Soft tissue, unspecified

ICD-10 code
M79.9

ICD-10 code description
Soft tissue disorder, unspecified

Primary outcomes

1

Description
pain

Timepoint
30 min before and 15 and 30 minutes after leaving the dressing room dressing room

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Vital signs (heart rate, blood pressure and respiratory rate)

Timepoint
30 min before and 15 and 30 minutes after leaving the dressing room dressing room

Method of measurement
manual measurement and digital blood pressure device

Intervention groups

1

Description
. Intervention1: in the first day, the base line of the vital signs and the pain of patients will be controlled in half an hour before entering into the dressing room and the patients inhale 5 drops of Damask Rose (Rose Damascene) essential oil 40% produced by Hyrad Company which was poured onto 10×10 cm gauze attached to collar of patients' shirt and then will go to dressing room. The pain and vital signs of the patients will be controlled in minutes of 15 and 30 after exiting of dressing room.
Category
Treatment - Drugs

2

Description
Intervention2: in the first day, the base line of the vital signs and the pain of patients will be controlled in half an hour before entering into the dressing room and the patients inhale 5 drops of distilled water as placebo which was poured onto 10×10 cm gauze attached to collar of patients' shirt and then will go to dressing room. The pain and vital signs of the patients will be controlled in minutes of 15 and 30 after exiting of dressing room. In the second day, in the both interventions, mentioned works will be conducted in the similar way again.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beast Therapeutic and Educational Center
Full name of responsible person
Mahdy Harorany
Street address
Nursing and Midwifery School, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr. Heydar Tavilani
Street address
Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.
City
Hamadan
Grant name
از محل یک درصد بودجه طرح های تحقیقاتی دانشگاه
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor of Research and Technology, 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
Department of Medical Surgical Nursing
Full name of responsible person
Dr. Ali Bikmoradi
Position
Medical Education Management
Other areas of specialty/work
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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