

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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) age 18 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)

##### Phone

+98 81 1838 0439

##### Email address

bikmoradi@umsha.ac.ir

##### 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) age 18 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

##### Street address

Department of Medical Surgical Nursing, Nursing and  
Midwifery School, Hamadan University of Medical  
Sciences, Shaheed Fahmideh Ave

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#### Contact

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##### Full name of responsible person

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##### Other areas of specialty/work

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**Person responsible for updating data****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****Street address**

Department of Medical Surgical Nursing, Nursing and Midwifery School, Hamadan University of Medical

**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*