

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of the concurrent effects of inhalation aromatherapy with Damask Rose and Lavender essential oils on the anesthetic drugs consumption in patients undergoing donor dressing change

#### Protocol summary

##### Study aim

Determining the concurrent effects of inhalation aromatherapy with Damask Rose and Lavender essential oils on the anesthetic drugs consumption and BIS scores in patients undergoing donor dressing change.

##### Design

A randomized controlled trial with control group, parallel, without blinding, using random sequences generated by SPSS software.

##### Settings and conduct

This study will be conducted in the burn unit of Imam Reza Hospital in Mashhad. Patients of the intervention group inhale Damask Rose and Lavender essential oils before change dressing, then anesthetic drugs are injected until the level of brain activity reaches the standard level. In the control group, anesthetic drugs will be administered without inhalation. Vital signs, respiratory indicators, and brain activity levels are monitored by monitoring, pulse oximetry, capnography and BIS.

##### Participants/Inclusion and exclusion criteria

Inclusion: Patients with second and third grade of burns, skin grafts at the burn site, donor anterior femur and filling the consent form. Exclusion: sensitivity to inhalation of Damask Rose and Lavender essential oils and the occurrence of special medical conditions.

##### Intervention groups

The Patients of the intervention group will inhale Damask Rose and Lavender essential oils before donor dressing change. Then anesthetic drugs are administered. The control group will receive only anesthetic drugs before donor dressing change.

##### Main outcome variables

The amount of anesthetic drugs required to reach the desired BIS and the duration of anesthesia in both groups will be recorded and compared.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171123037599N2**

Registration date: **2018-09-29, 1397/07/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-29, 1397/07/07**

Update count: **0**

##### Registration date

2018-09-29, 1397/07/07

##### Registrant information

##### Name

Razieh Froutan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3881 4241

##### Email address

froutanr@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-25, 1397/06/03

##### Expected recruitment end date

2019-07-22, 1398/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the concurrent effects of inhalation aromatherapy with Damask Rose and Lavender essential oils on the anesthetic drugs consumption in patients undergoing donor dressing change

## Public title

The concurrent effects of inhalation aromatherapy with Damask Rose and Lavender essential oils on the amount of anesthetic drugs consumption in patients undergoing donor place dressing change

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with second and third-degree burns Need to skin graft Donor location in the anterior femur Filling out the informed consent

### Exclusion criteria:

Being sensitive to inhalation of Lavender and Damask Rose Occurrence of special medical conditions

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random assignment is applied using random sequences generated by SPSS software to assign patients to intervention and control groups.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Ebne- Sina Street, School of Nursing and Midwifery, Mashhad,Iran.

##### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913199

#### Approval date

2018-07-30, 1397/05/08

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1397.027

## Health conditions studied

### 1

#### Description of health condition studied

Burn

#### ICD-10 code

T30.2

#### ICD-10 code description

Burn of second degree, body region unspecified

## Primary outcomes

### 1

#### Description

Reducing anesthetic drug consumption in patients undergoing donor dressing change

#### Timepoint

The amount of anesthetic drugs consumption every 45 seconds after beginning the sedation.

#### Method of measurement

milligram

### 2

#### Description

Measuring the brain activity using BIS device connected to the patient.

#### Timepoint

Every five minutes after sedation begins, by an technician.

#### Method of measurement

By reading the BIS score on device.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Before changing the donor's dressing, patients will inhale 5 drops of Damask Rose (40%) and 7 drops of Lavender (10%) essential oils concurrently but with two separate aerators. Anesthetic drugs (midazolam, fentanil and ketamine) are administered until the level of brain activity is reached to the standard level that is measured by the BIS (Bispectral index).

**Category**

Other

**2****Description**

Control group: Before changing the donor's dressing, anesthetic drugs (midazolam, fentanyl and ketamine) are administered until the level of brain activity is reached to the standard level by the BIS (Bispectral index).

**Category**

Other

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

Imam Reza hospital

**Full name of responsible person**

Razieh Froutan

**Street address**

Nursing faculty,Ebn-e Sina Street ,Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913119

**Phone**

+98 51 3859 1511

**Email**

froutanr@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Deputy of Research and Technology

**Street address**

Ghoreishi building,Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 3841 2081

**Email**

froutanr@mums.ac.ir

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

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Razieh Froutan

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Ebne-Sina Street Mashhad, Iran

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

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Assistant Professor

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Consent form sample analysis method study result final manuscript

### When the data will become available and for how long

One year after publication

### To whom data/document is available

academic researcher by demand

### Under which criteria data/document could be used

for systematic reviews and meta-analysis

### From where data/document is obtainable

email:froutanr@mums.ac.ir

### What processes are involved for a request to access data/document

After Email reception.

### Comments