

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Effect of inhalation aromatherapy with Damask Rose on Pain severity, anxiety and hemodynamic parameters in patients undergoing cataract surgery with local anesthesia

#### Protocol summary

##### Study aim

Determining the effect of inhalation aromatherapy with Damask Rose on pain intensity, anxiety and hemodynamic parameters of patients undergoing cataract surgery with local anesthesia.

##### Design

Clinical trial with control group, double-blind, randomized on 152 patients. Blocking method will be used for randomization.

##### Settings and conduct

The intervention will be carried out on the groups of Damask Rose and placebo for 20 minutes. The intervention will be in such a way that the researcher will fix the pad impregnated with the Damask Rose and normal saline inside the oxygen mask and the patient will also inhale the Damask Rose during the surgery along with receiving oxygen. In the placebo group, the pad will be soaked in normal saline. This study will be conducted in the hospitals of Qom University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include : the ability to communicate, not being allergic to herbal medicines, not being addicted to drugs and alcohol, no mental disorder, no olfactory disorder, not being a smoker, being over 60 years old Exclusion criteria include: the presence of respiratory and allergic problems, the patient's unwillingness to continue to cooperate

##### Intervention groups

The intervention will be in the form of fixing the pad impregnated with Damask Rose scent and normal saline inside the oxygen mask using glue, and the patient will also inhale Damask Rose scent during the surgery along with receiving oxygen, which is done routinely. In the placebo group, the pad will be soaked in normal saline

##### Main outcome variables

The pain; anxiety; Hemodynamic symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221205056718N3**

Registration date: **2024-02-14, 1402/11/25**

Registration timing: **prospective**

Last update: **2024-02-14, 1402/11/25**

Update count: **0**

##### Registration date

2024-02-14, 1402/11/25

##### Registrant information

##### Name

Hossein Sharafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3197 1087

##### Email address

hsharafi@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-06, 1403/01/18

##### Expected recruitment end date

2024-09-21, 1403/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of inhalation aromatherapy with Damask Rose on Pain severity, anxiety and hemodynamic parameters in patients undergoing cataract surgery with local anesthesia

## Public title

Investigating the effect of Damask Rose on pain intensity, anxiety and vital signs

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Ability to communicate Insensitivity to herbal medicines No drug addiction and alcohol addiction No mental disorder No olfactory disorder Not smoking Over 60 years of age The same anesthesiologist and surgeon The amount of fluo-oxygen is the same in all samples

### Exclusion criteria:

Use of other herbal medicine by the patient Respiratory and allergic problems The patient's unwillingness to continue to cooperate Using more or less than normal amount of oxygen Lack of consciousness of the patient during surgery and discharge of the patient before the end of the study

## Age

From **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **152**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients who are eligible for the study are entered into the study using the available method and are randomly assigned to two intervention and control groups using the block method (blocks of four and with an allocation ratio of 1:1 using a random number table). . For example, the first four participants enrolled form the first block and the next four form the next block, and so randomization occurs within blocks, so with blocks of size four there are six possible patterns: AABB, ABAB, ABBA , BAAB, BABA, and BBAA, each block is randomized based on one of these six patterns, and the patterns are chosen randomly and generally independently from block to block

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, before starting the research, the participants will not be aware of the objectives of the research, and after the study, the objectives of the research will be explained to them, and if the patient does not want to use the scent, he will be excluded from the study. The two nurses who complete the evaluation

questionnaires will not know about the two control and intervention groups due to the spread of low-scented smell and the use of aromatic gas inside their masks. The researcher will conduct the intervention and monitor the data recording process

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Qom University of Medical Sciences

##### Street address

Operating room department, Paramedical faculty, Qom University of Medical Sciences, university campus

##### City

Qom

##### Province

Ghoum

##### Postal code

3713649373

#### Approval date

2023-10-02, 1402/07/10

#### Ethics committee reference number

IR.MUQ.REC.1402.214

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

Pain associated with cataract surgery

#### Timepoint

Before the intervention, immediately after the intervention and 15 minutes after leaving the operating room

#### Method of measurement

VAS scale

## Secondary outcomes

### 1

#### Description

Hemodynamic parameters

#### Timepoint

During the surgical procedure at the same time as aromatherapy, the changes in hemodynamic symptoms (blood pressure-heart rate) of the patient are recorded every 5 minutes.

#### Method of measurement

Digital heart monitoring system

## Intervention groups

### 1

#### Description

Intervention group: The pad impregnated with Damask Rose is fixed inside the oxygen mask using glue, and the patient will also smell Damask Rose during the surgery along with receiving oxygen, which is done routinely. Damask Rose (group A) and placebo (group B) will be administered for 20 minutes.

#### Category

Treatment - Other

### 2

#### Description

Control group: The intervention will be to fix the pad soaked in normal saline inside the oxygen mask using glue, and the patient will also smell normal saline during the surgery along with receiving oxygen, which is done routinely.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Qom Kamkar-Arabnia Hospital

##### Full name of responsible person

Dr. Seyed Alireza Chavoshizadeh

##### Street address

19 Dey. St ,Qom

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##### Web page address

<http://kamkar.muq.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ghous University of Medical Sciences

##### Full name of responsible person

Rahim Aali

##### Street address

Jihad University Alley, Safashehr St, Qom

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ghous 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

Ghous University of Medical Sciences

##### Full name of responsible person

Hossein sharafi

##### Position

Instructor

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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

Yes - There is a plan to make this available

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

Effect of inhalation aromatherapy with Damask Rose on Pain severity, anxiety and hemodynamic parameters in patients undergoing cataract surgery with local anesthesia

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

The second half of 2024

### To whom data/document is available

There is no restriction on access to the results

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

There are no restrictions after de-identifying people

### From where data/document is obtainable

hossein sharafi email:h\_sharafi68@yahoo.com  
hsharafi@muq.ac.ir tell:00989173596990

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

The request for the data that is irrefutably identified will be made through the e-mail introduced by the researcher, and the request will be reviewed in less than 10 days and the requested data will be provided to the requester.

### Comments