Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Rahim Aali
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Web page address
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Hossein sharafi
Position
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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