

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of essential oil of Lavender inhalation on open-heart surgery pain

#### Protocol summary

##### Summary

The goal of this study is evaluating the effects of inhalation of Lavender essential oil on the pain of open-heart surgery. The main complaint of patients after open-heart surgery is chest pain. Due to the side effects of opioids, it is important to use a non-invasive way to effectively relieve pain including aromatherapy with analgesics. This study is a clinical single-blind trial. The study was conducted on 40 patients who had open-heart surgery in the Cardiac ICU of two Hospitals of Tehran University of Medical Sciences, 2012. The level of patient's pain before and after aromatherapy were analyzed by paired t-tests and chi-square and Fishers' exact is used to investigate the relationship between demographic characteristics and pain. Statistical significance was accepted for  $P < 0.05$ . Criteria included: full Consciousness, spontaneous breathing ability and not using synthetic opioids within 2 hours before extubation. Also, some exclusion criteria were set in this research. The patients that needed medical intervention during the inhalation, or in case of allergies, respiratory problems and emergencies, were excluded from this research. After extubation, the patients were asked to mark the intensity of their pain using the visual analogue scale. Then, a cotton swab which was impregnated with 2 drops of Lavender essential oil 2% was placed in their oxygen mask, and they got breath for 10 minutes. Thirty minutes after aromatherapy, they were asked to re-mark their pain intensity. The level of patient's pain before and after aromatherapy were compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013061813711N1**

Registration date: **2013-07-16, 1392/04/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-16, 1392/04/25

##### Registrant information

###### Name

Armaiti Salamati

###### Name of organization / entity

Islamic Azad University, Tehran Medical Branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4490 1139

###### Email address

smashouf@iautmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Islamic Azad University Tehran Medical Branch

##### Expected recruitment start date

2012-11-21, 1391/09/01

##### Expected recruitment end date

2012-12-21, 1391/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of essential oil of Lavender inhalation on open-heart surgery pain

##### Public title

Effect of essential oil of Lavender inhalation on open-heart surgery pain

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Criteria included: between 18 and 65 full Consciousness,

spontaneous breathing ability and not using synthetic opioids within 2 hours before extubation. Exclusion criteria: needed medical intervention during the inhalation in case of allergies, respiratory problems and emergencies

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Islamic Azad University Tehran Medical Branch

**Street address**

Tehran

**City**

Tehran

**Postal code****Approval date**

2012-05-18, 1391/02/29

**Ethics committee reference number**

13610403902018

**Health conditions studied****1****Description of health condition studied**

open-heart surgery

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain

**Timepoint**

one hour after Lavender inhalation

**Method of measurement**

Pain measurement

**Secondary outcomes**

empty

**Intervention groups****1****Description**

A cotton swab which was impregnated with 2 drops of Lavender essential oil 2% was placed in their oxygen mask, and they got breath for 10 minutes

**Category**

Treatment - Drugs

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

Tehran Heart center

**Full name of responsible person****Street address****City**

Tehran

**2****Recruitment center****Name of recruitment center**

Moheb Hospital

**Full name of responsible person****Street address****City**

Tehran

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

Research Department of Islamic Azad University Tehran Medical Branch

**Full name of responsible person**

Naghypour (Research Dep of Azad University)

**Street address**

Tehran

**City**

Tehran

**Grant name****Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Research Department of Islamic Azad University Tehran  
Medical Branch

**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**  
*empty*

**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Armaiti Salamati

**Position**  
MS

**Other areas of specialty/work**

**Street address**  
Tehran

**City**  
Tehran

**Postal code**

**Phone**  
+98 21 4490 1139

**Fax**

**Email**  
arisalamati@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Armaiti Salamati

**Position**  
MS

**Other areas of specialty/work**

**Street address**  
Tehran

**City**  
Tehran

**Postal code**

**Phone**  
+98 21 4490 1139

**Fax**

**Email**  
arisalamati@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**  
Islamic Azad University Tehran Medical Branch

**Full name of responsible person**  
Armaiti Salamati

**Position**  
MS in Nursing

**Other areas of specialty/work**

**Street address**  
Tehran

**City**  
Tehran

**Postal code**

**Phone**  
+98 21 4490 1139

**Fax**

**Email**  
arisalamati@gmail.com

**Web page address**

## 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*