

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of aroma therapy versus placebo on the pain and anxiety due to sternotomy in patients after open heart surgery: a double blinded randomized controlled trial

#### Protocol summary

##### Summary

Objectives: To assess the effect of aroma therapy on the pain and anxiety due to sternotomy in patients after open heart surgery. Design: A double blinded randomized controlled trial. Setting and conduct: The patients underwent open heart surgery with GCS equal to 15 will be enrolled into the study. Participants including major eligibility criteria: The patients with any one of the following characteristics will be excluded from the study; (a) having pulmonary problems; (b) narcotic and alcohol addiction or drug abuse; (c) scent impairment; (d) history of convulsion; (e) using anti-anxiety drugs; (f) intubation for more than 24 hours. Intervention: Pouring two drops of 2% lavender oil produced by Barij Esans Company into the oxygen mask and patients began inhale through the mask for 20 minutes in the second and third days after surgery. Control: Pouring two drops of distilled water into the oxygen mask and patients began inhale through the mask for 20 minutes in the second and third days after surgery. Primary outcome measures: Relief of pain after surgery using ruler scaled from zero to ten. Secondary outcome measures: Assessment of anxiety using Spielberg questionnaire, and stress and depression using DASS 21 questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203299014N9**  
Registration date: **2012-07-02, 1391/04/12**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-07-02, 1391/04/12

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2012-07-22, 1391/05/01

##### Expected recruitment end date

2013-02-19, 1391/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of aroma therapy versus placebo on the pain and anxiety due to sternotomy in patients after open heart surgery: a double blinded randomized controlled trial

##### Public title

The effect of aroma therapy versus placebo on the pain

and anxiety due to sternotomy in patients after open heart surgery

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

The patients underwent open heart surgery with GCS equal to 15 will be enrolled into the study. The patients with any one of the following characteristics will be excluded from the study; (a) having pulmonary problems; (b) narcotic and alcohol addiction or drug abuse; (c) scent impairment; (d) history of convulsion; (e) using anti-anxiety drugs; (f) intubation for more than 24 hours.

#### **Age**

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

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Local Human Subject Review board

###### **Street address**

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

###### **City**

Hamadan

###### **Postal code**

6517838695

##### **Approval date**

2012-06-26, 1391/04/06

##### **Ethics committee reference number**

D/P/16/35/9/1116

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Chest pain post sternotomy after open heart surgery

##### **ICD-10 code**

I97

##### **ICD-10 code description**

Postprocedural disorders of circulatory system, not elsewhere classified

### **Primary outcomes**

#### **1**

##### **Description**

Relief of pain due to sternotomy post open heart surgery

##### **Timepoint**

24 hours

##### **Method of measurement**

Ruler scaled from zero to ten

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Pouring two drops of 2% lavender oil produced by Barij Esans Company into the oxygen mask and patients began inhale through the mask for 20 minutes in the second and third days after surgery.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Pouring two drops of distilled water into the oxygen mask and patients began inhale through the mask for 20 minutes in the second and third days after surgery.

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Ekbatan Hospital

###### **Full name of responsible person**

Dr Ali Beikmoradi

###### **Street address**

Department of Internal Medicine and Surgery, 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 for Research and Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Ahmad tavilani

**Street address**

Financial support from one percent budget specified  
to research projects

**City**

Hamadan

**Grant name**

از محل يك درصد بودجه طرحهاي تحقيقاتي دانشگاه

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

Yes

**Title of funding source**

Vice Chancellor for 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**

Research Center for Health Sciences, Department of  
Epidemiology & Biostatistics

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

MD, PhD, Assistant Professor of Epidemiology

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Department of Internal Medicine and Surgery

**Full name of responsible person**

Dr Ali Beikmoradi

**Position**

PhD

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## Person responsible for updating data

**Contact****Contact****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*