

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The effect of inhalation of aromatherapy (Lavender Essential Oil) on post operative discectomy pain

#### Protocol summary

##### Summary

This study is a clinical trial of an quasi experimental study. After getting permission from the authorities and informed consent of the participants in the study, patients undergoing discectomy through a available sampling of the number (60) were selected and random allocation block in the two groups will. Inclusion criteria were: age over 18 years, having the ability to understand language of Persian or Turkish, Lacking a history of allergy to plants, lack of pregnancy, lack of hypertension, The lack of clotting disorders and Having sense of smell and vision healthy. Since the use drug is in the form of inhaler and the pain of intensity will be evaluated using the VAS tool, sense of smell and vision before entering the people in the study by using test sense of smell, and visual acuity will be examined. In this study, the experimental group, the essential oil of lavender will be prepared of the company of Kashan Barych Esance, with the right concentration (recommended texts) through inhalation of used and then, at a certain level of pain intensity will be measured by using the VAS. Similarly placebo in the control group by the same method by the experimental group used and then pain intensity will be evaluated by means of tool VAS. In addition, in order to assess the impact of lavender essential oil compared with placebo, pain intensity in both groups before and after the intervention will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015070421403N1**

Registration date: **2015-07-04, 1394/04/13**

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

Last update:

Update count: **0**

##### Registration date

2015-07-04, 1394/04/13

##### Registrant information

###### Name

Gholamreza Arjmand

###### Name of organization / entity

Zanjan University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3336 5980

###### Email address

gholamrezaarjmand1981@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Financial resources of the project will be provided by Zanjan University of Medical Sciences

##### Expected recruitment start date

2015-04-30, 1394/02/10

##### Expected recruitment end date

2015-10-07, 1394/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of inhalation of aromatherapy (Lavender Essential Oil) on post operative discectomy pain

##### Public title

The effect of inhalation of aromatherapy (Lavender Essential Oil) on post operative discectomy pain

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: having a willingness to participate in the study; Having a discectomy surgery of lumbar disc; with full awareness and cooperation; Having a good sense of smell; Having a healthy state of mind and vision to see and understand the tool VAS (visual analog scale); age 18 and older; Having the ability to understand language, Persian or Turkish; lacking a history of allergy to plants; The lack of pregnancy, high blood pressure and coagulation Exclusion criteria: Patients with complications such as bleeding; patients undergoing oxygen therapy; The patient's unwillingness to participate in the study after the first intervention because patients may experience unpleasant feeling of these fragrances for various reasons.

### **Age**

From **18 years** old to **139 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**

### **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**

Zanjan University of Medical Sciences and Health Services

##### **Street address**

Zanjan, Azadi Square, The beginning of the Islamic Republic Boulevard, Central Chiefs Zanjan University of Medical Sciences

##### **City**

Zanjan

##### **Postal code**

45156-13191

##### **Approval date**

2015-02-24, 1393/12/05

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

ZUMS.REC.1393.233

## **Health conditions studied**

### **1**

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

Pain after lumbar disc surgery

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

Y45.0

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

Opioids and related analgesics

### **2**

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

Pain after lumbar disc surgery

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

M51.2

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

Other specified intervertebral disc displacement

## **Primary outcomes**

### **1**

#### **Description**

Pain severity After Surgery

#### **Timepoint**

4, 8 , 12 hours after the onset of pain after surgery

#### **Method of measurement**

Visual Analog Scale and record the questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

The postoperative opioid consumption

#### **Timepoint**

During the intervention

#### **Method of measurement**

Through patient records

## **Intervention groups**

### **1**

#### **Description**

Intervention in interventional groups: a total of 3 times intervention in the first day after surgery (4, 8 and 12 hours after the onset of pain after surgery) done for patients. Description work In this way three drops of aromatherapy blend containing Lavender essence 10% (provided by The Barij Essence Pharmaceutical Compnay) were poured on cotton pellet, and the patient was asked to inhale it for 5 minutes from a distance of 10 cm; and pain score was measured using the VAS again, (Intervention with drug use)

#### **Category**

Treatment - Drugs

**Description**

Intervention in the control group: a total of 3 times intervention in the first day after surgery (4, 8 and 12 hours after the onset of pain after surgery) done for patients. Description work In this way three drops three drops of sweet almond oil (placebo) (provided by The Barij Essence Pharmaceutical Compnay) were poured on cotton pellet, and the patient was asked to inhale it for 5 minutes from a distance of 10 cm; and pain score was measured using the VAS again ( with placebo use).

**Category**

Treatment - Drugs

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

Shohada Hospital Tabriz

**Full name of responsible person**

DR.Iraj Lutfinia (specialist neurosurgery, Professor) -  
DR. Mohammad shimia (specialist neurosurger,

**Street address**

Tabriz - Golshahr - Shohada Hospital

**City**

Tabriz

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Soghrat Faghihzadeh

**Street address**

Zanjan, Azadi Square, The beginning of the Islamic  
Republic Boulevard, Central Chiefs Zanjan University  
of Medical Sciences

**City**

Zanjan

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

Yes

**Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Gholamreza Arjmand

**Position**

McS in Critical Care Nursing

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

Tabriz - Golshahr - Shohada Hospital

**City**

Tabriz

**Postal code**

5167846171

**Phone**

+98 41 3389 3221

**Fax**

+98 41 3389 3337

**Email**

gholamrezaarjmand1981@yahoo.com

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Nasrin Bahram nezhad

**Position**

PhD in community health

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

Zanjan, Azadi Square , The beginning of the Islamic  
Republic Boulevard, Zanjan University of Medical  
Sciences

**City**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24334206519

**Fax**

+98 24 3342 4774

**Email**

Nasrin4807@yahoo.com

**Web page address**

http://www.zums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Gholamreza Arjmand

**Position**

McS in Critical Care Nursing

**Other areas of specialty/work**

**Street address**

Tabriz - Golshahr - Shohada Hospital

**City**

Tabriz

**Postal code**

5167846171

**Phone**

+98 41 3389 3221

**Fax**

+98 41 3389 3337

**Email**

gholamrezaarjmand1981@yahoo.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*