

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Clinical trial the effect of aroma therapy on severity of anxiety in patient before crusher surgery through the skin , by spinal anesthesia compared with patients with routine care

#### Protocol summary

##### Summary

The aim of this study is to investigate the effects of aromatherapy on anxiety before crusher surgery through the skin. The level of anxiety, as the main variable, will be measured using standard questionnaires before and the morning of surgery. The used aroma in the intervention group is that of roses. The study population includes all patients admitted to Jahrom Peymanieh Hospital for crusher surgery through the skin with the spinal anesthesia. People developing chronic and cancerous pain, hearing or speech loss, lack of mental health and sensitivity to roses were excluded from the study. The sample size was estimated 38 people. Prior to the surgery, patients were divided into intervention and control groups through random allocation method using random numbers table. In the control group, without any interference, anesthesia technician will get his patient to complete questionnaire the day before and the morning of surgery. In the intervention group, the technician will attend at the bedside the day before the surgery and at first get the patient to complete the questionnaire. Then the morning of surgery, he will impregnate a piece of cotton with the essence of rose 4 hours prior to surgery and will install it on the patient's clothing. The patient breathes normally during this period. After the patient's entering to the operating room, Spielberger questionnaire will be again completed by anesthesia technicians. All patients need to have informed consent to participate in the study. It is expected that the performed intervention results in decreasing anxiety and increasing satisfaction with this non-pharmacological methods of anxiety control.

#### General information

##### Acronym

42 </option> <option value="43">

##### IRCT registration information

IRCT registration number: **IRCT2016020414049N3**

Registration date: **2016-06-07, 1395/03/18**

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

Last update:

Update count: **0**

##### Registration date

2016-06-07, 1395/03/18

##### Registrant information

###### Name

Ali Abbasi Jahromi

###### Name of organization / entity

Jahrom University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 79 1334 1501

###### Email address

abbasija@jums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Jahrom University of Medical Sciences

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### Expected recruitment end date

2017-12-01, 1396/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Clinical trial the effect of aroma therapy on severity of anxiety in patient before crusher surgery through the skin , by spinal anesthesia compared with patients with routine care

## Public title

The Effect of Aromatherapy on patient anxiety before surgery

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion Criteria: All patients who are about to undergo crusher surgery through the skin in Peymanieh Hospital affiliated with Jahrom University of Medical Sciences and spinal anesthesia can be done for them. Informed consent to participate in this study is among the main inclusion criteria. Exclusion criteria: Sensitivity to roses, education lower than primary, developing chronic and cancerous pain, hearing or speech loss, lack of mental health, chronic use of drugs and sedatives, Unstable hemodynamic status, expressed dissatisfaction to continue research.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 38

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Double blind method has been used in this study so that the 1- The volunteer and 2- The person who records anxiety are not aware of measurement methods in intervention and control group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic Committee of Jahrom University of Medical Sciences

##### Street address

School of Nursing and Midwifery, Motahhari Blvd, Jahrom

#### City

Jahrom

#### Postal code

#### Approval date

2016-02-03, 1394/11/14

#### Ethics committee reference number

JUMS.Rec.1394.180

## Health conditions studied

### 1

#### Description of health condition studied

The level of anxiety after Aroma Therapy

#### ICD-10 code

F48.8

#### ICD-10 code description

Other specified neurotic disorders

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

before intervention and then Every 4 hours before intervention Within 24 hours(1 days)

#### Method of measurement

Spielberger questionnaire

## Secondary outcomes

### 1

#### Description

Vital signs

#### Timepoint

Before surgery

#### Method of measurement

Monitoring Blood pressure, Heart Rate, Temperature, Breathing

## Intervention groups

### 1

#### Description

In the control group, patients will receive the usual care after being admitted to the ward and anxiety will be recorded prior to the operation.

#### Category

N/A

### 2

#### Description

In the intervention group, Researcher will impregnate a piece of cotton with the essence of rose 4 hours prior to

surgery and will install it on the patient's clothing. Then the patient breathes normally during this period. After the patient's entering to the operating room, Spielberger questionnaire will be again completed by anesthesia technicians

**Category**

Treatment - Other

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

Peymanieh Hospital

**Full name of responsible person**

Zarean Vahid

**Street address**

Jahrom, Valiye Asr Street

**City**

Jahrom

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

Vice chancellor for research, Jahrom University of Medical Sciences

**Full name of responsible person**

Solh Ju Kavos

**Street address**

Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom

**City**

Jahrom

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

Yes

**Title of funding source**

Vice chancellor for research, Jahrom 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**

Jahrom University of Medical Sciences

**Full name of responsible person**

Zarean Vahid

**Position**

Anesthesia Undergraduate Student

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

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

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**Full name of responsible person**

Abbasi Jahromi Ali

**Position**

Faculty member

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Vahid Zarean

**Position**

Anesthesia Undergraduate Student

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**Fax****Email**

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**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*