

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)

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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

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

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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

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

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Faculty member

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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