

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### Comparing effectiveness of Damask rose and lavender scent on severity of pain and anxiety after Cesarean section, through women.

#### Protocol summary

##### Summary

Purpose of the study is to discuss the effect of aromatherapy on severity of pain and anxiety after cesarean section. This measurement would be done last to 48 hours after surgery by Spielberg-er standard questionnaire and visual analogue scale. Scent consumed in intervention group was Damask rose and Lavender aroma. Studied population are all women who referred to Motaharie hospital in Jahrom, being operated by cesarean method that achieve participation minimal. Sample size estimation is 90 person. Before surgery, patients divided into three groups by simple random allocation: 1) Instance 2) Intervention(with Lavender) 3) Intervention(with Damask rose) At first group, after admitting patient into maternity ward, anxiety and pain level will be recorded without any further proceedings. At second group, after admission, researcher would dipped cotton with lavender aroma and attach it to patient clothing. At third group, researcher would dipped cotton with damask rose aroma and attach it to patient clothing as well. Then their level of anxiety and pain will be recorded. After surgery and further entry to the ward, necessary interventions would be done beside pain and anxiety measurements every 30 minutes for duration of six hours. Patients suffering from chronic and cancer pains, psycho-social problems and those who are allergic to mentioned flavors will be excluded. All patients should be consciously involved in the study. It is expected that interventions cause anxiety and pain relief, beside satisfaction increase, from this non-pharmacological pain control method.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017092814049N7**

Registration date: **2017-11-18, 1396/08/27**

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

Last update:

Update count: **0**

##### Registration date

2017-11-18, 1396/08/27

##### 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

2017-10-12, 1396/07/20

##### Expected recruitment end date

2018-03-11, 1396/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing effectiveness of Damask rose and lavender scent on severity of pain and anxiety after Cesarean section, through women.

##### Public title

Post-surgery effect of aromatherapy on pain and anxiety

##### Purpose

Supportive

**Inclusion/Exclusion criteria**  
 Inclusion Criteria: All patients who are about to undergo crusher surgery through the skin in Motahari 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 and Lavender; 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**  
 Female

**Phase**  
 N/A

**Groups that have been masked**  
*No information*

**Sample size**  
 Target sample size: **90**

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

**Randomization description**

**Blinding (investigator's opinion)**  
 Double blinded

**Blinding description**

**Placebo**  
 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 pain and anxiety are not aware of measurement methods in intervention and control group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

##### Street address

School of Nursing and Midwifery, Motahhari Blvd, Jahrom

##### City

Jahrom

##### Postal code

#### Approval date

2017-09-20, 1396/06/29

#### Ethics committee reference number

JUMS.REC.1396.056

## Health conditions studied

### 1

#### Description of health condition studied

Severity of pain after Aroma Therapy

#### ICD-10 code

R52.0

#### ICD-10 code description

Acute pain

### 2

#### 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

Pain in the Abdomen and Pelvis

#### Timepoint

Every 6 hours after surgery With in 24 hours(1 days)

#### Method of measurement

On base of VAS

### 2

#### Description

Vital signs

#### Timepoint

after surgery

#### Method of measurement

Monitoring Blood pressure, Heart Rate, Temperature, Breathing

## Secondary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Every 4 hours after intervention With in 24 hours(1 day)

#### Method of measurement

Spielberger questionnaire

## Intervention groups

### 1

#### Description

After admitting patient into maternity ward, anxiety and pain level will be recorded without any further proceedings.

#### Category

N/A

**2**

**Description**

At first intervened group, three drops of aromatherapy combination consist of lavender essence would be dipped on cotton; then the patient would be asked to smell it from 10 centimeters far for duration of 30 minutes.

**Category**

N/A

**3**

**Description**

At second intervened group, three drops of aromatherapy combination consist of damask rose essence would be dipped on cotton; then the patient would be asked to smell it from 10 centimeters far for duration of 30 minutes.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Motahhari Hospital

**Full name of responsible person**

Vahid Zarean

**Street address**

Motahhari Blvd, Jahrom Jahrom Fars

**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**

Vahid Zarean

**Position**

Anesthesia Undergraduate Student

**Other areas of specialty/work**

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**Full name of responsible person**

Abbasi Jahromi Ali

**Position**

Faculty member

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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Jahrom

**City**

Jahrom

**Postal code**

**Phone**

00

**Fax**

**Email**

**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*