

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effect of geranium (pelargonium graveolens) and orange (citrus sinesis) aroma on anxiety and vital signs in first stage of labor in primiparous women

#### Protocol summary

##### Summary

**Objectives:** This study compared the effects of aromatherapy geranium and orange essential oil in first stage of labor in nulliparous on the anxiety and vital sign. **Design:** parallel. **Setting and conduct:** This study is a three-group of randomized clinical trial. The sample consisted of 150 nulliparous admitted to the Bojnoord Bint al-Huda hospital. After take consent of the participants were randomly divided into 3 groups. One group would receive geranium essential oil (50) and orange oil group (50) and a distilled water (50). Before and 20 minutes after intervention are examined to STAI anxiety questionnaire, physiological parameters would record. **Participants including:** Inclusion criteria for this study included nulliparous women to full-term pregnancy, with a single fetus, cervix dilatation of 3-5cm, haven't chronic disease, no colds and haven't nasal congestio, anosmia, lack of sensitivity to smell specific experience of breath smells particular (which bad recalls memories or stress), the use of sedatives or anti-anxiety in 3 hours before the experiment, no known mental illness, no history of epilepsy and asthma, lack of fetal distress, failure to induce labor there was a high risk pregnancy. **Exclusion criteria for the study,** the firm's unwillingness to continue the study of fetal distress or impairment in labor progress during the intervention, use of pain medication during labor induction or intervention. **Intervention:** One group, orange essential oil 2% and other group geranium oil 2% and in control group distilled water 2drops would receive on non-absorbent fabric, the clothing will connect. **Main outcome measures** Intervention. Anxiety, physiological parameters, including systolic blood pressure, diastolic blood pressure, respiration and pulse.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012111811515N1**  
Registration date: **2013-09-15, 1392/06/24**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-09-15, 1392/06/24

##### Registrant information

##### Name

Fahimeh Rashidi Fakari

##### Name of organization / entity

North Khorasan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 4224 6095

##### Email address

rashidif85@nkums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Medical Sciences of Vice chancellor for research, North Khorasan University

##### Expected recruitment start date

2012-08-22, 1391/06/01

##### Expected recruitment end date

2013-10-23, 1392/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of geranium (pelargonium graveolens) and orange (citrus sinensis) aroma on anxiety and vital signs in first stage of labor in primiparous women

**Public title**

The effect of aromatherapy on anxiety and vital signs

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

included nulliparous women; full-term pregnancy (37-42); ages 18-35; with a single fetus; dilatation of 3-5 cm ; haven't chronic disease; no colds and haven't nasal congestion; anosmia; lack of sensitivity to smell specific experience of breath smells particular (which bad recalls memories or stress); the use of sedatives or anti-anxiety in 3 hours before the experiment; no known mental illness; no history of epilepsy and asthma; lack of fetal distress; failure to induce labor there was a high risk pregnancy. Exclusion criteria for the study; the firm's unwillingness to continue the study of fetal distress or impairment in labor progress during the intervention; use of pain medication during labor induction or intervention

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of North Khorasan University of Medical Sciences

**Street address**

20 Number, Berenji street, Bojnord, North Khorasan

**City**

Bojnord

**Postal code****Approval date**

2012-05-23, 1391/03/03

**Ethics committee reference number**

91/p/349

**Health conditions studied****1****Description of health condition studied**

Anxiety Level

**ICD-10 code**

F41.9

**ICD-10 code description**

Anxiety disorder, unspecified

**Primary outcomes****1****Description**

anxiety level of first phase of labor

**Timepoint**

Before and 20 min after intervention

**Method of measurement**

Spielberger state-trait

**Secondary outcomes****1****Description**

pulse rate

**Timepoint**

Before and 20 minutes after intervention

**Method of measurement**

examination

**2****Description**

Systolic BP

**Timepoint**

Before and 20 minutes after intervention

**Method of measurement**

examination

**3****Description**

Diastolic BP

**Timepoint**

Before and 20 minutes after intervention

**Method of measurement**

examination

**4****Description**

pain intensity

#### **Timepoint**

Before and 20 minutes after intervention

#### **Method of measurement**

VAS pain scale

### **Intervention groups**

#### **1**

##### **Description**

In test one (oil of orange peels) and experimental group II (Essence Geranium), on fabric, non-absorbent, the clothing connected. Before and 20 minutes after intervention anxiety inventory STAI, physiological parameters by examining pain Pain was measured using visual analog scales.

##### **Category**

Prevention

#### **2**

##### **Description**

In the control group, distilled water onto non-absorbent fabric, the clothing connected. Before and 20 minutes after intervention STAI anxiety questionnaire, physiological parameters were recorded by the examiner and VAS pain scale.

##### **Category**

Placebo

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Bentul Hoda Hospital Bojnourd, Bojnourd, North Khorasan

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

Alieh Mortazavi

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

Bentul Hoda Hospital Bojnourd, Zaieshgah Street , Bojnourd, North Khorasan

###### **City**

Bojnourd

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Medical Sciences of Vice chancellor for research, North Khorasan University

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

Arash Aabri

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

20 Number, Berenji street, Bojnord

###### **City**

Bojnord

###### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Medical Sciences of Vice chancellor for research, North Khorasan University

#### **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**

North Khorasan University of Medical Sciences

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

Maboobeh Tabatabaee Chehr

##### **Position**

Mentor, Msc of midwifery

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### **Person responsible for scientific inquiries**

#### **Contact**

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## Person responsible for updating data

### Contact

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## 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*