

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

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Name of organization / entity

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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

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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

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

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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

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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

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

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Full name of responsible person

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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