

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparative assessment of effect of aromatherapy with essential oil of Peppermint and essential oil of Cloves on pain intensity and anxiety in first stage of labor on primiparous women.

Protocol summary

Summary

The aim of this study was to compare the effects of aromatherapy by essential oil of Peppermint and essential oil of Cloves on pain intensity and anxiety in first stage of labor in primiparous women that referred to Kamali Hospital in Karaj. In this single blind randomized clinical trial, a table of random numbers was used to randomly allocate the eligible women Peppermint group and Cloves group (63 in each group). The inclusion criteria were: primiparous in the age range of 18 to 35 years, term pregnancy, single pregnancy, fetal vertex presentation, not use of analgesic drug in last 8 hours and not having obstetric complications. The exclusion criteria were: Peppermint or Clove allergy or intolerance. Before beginning of intervention demographic questionnaire and Spielberger questionnaire will be completed and using of pain ruler will be explained to patients. In active phase from 4 cm of cervix dilatation aromatherapy will be started and intensity of labor pain after 20 minute of beginning of aromatherapy will be measured and aromatherapy until end of labor will be continued. In the first group, 0.2 ml essential oil of Peppermint and in the second group, 0.2 ml essential oil of Cloves will be treated to gas and attached to dresses collar of women and essential every half hour will be repeated. Intensity of labor pain will be measured in 4,5 cm, 6,7 cm and 8,10 cm of cervix dilatation. Anxiety will be measured in 4,3 cm and 8,10 cm of cervix dilatation. The data from the pain and anxiety of both groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512253860N22**
Registration date: **2016-02-11, 1394/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-11, 1394/11/22

Registrant information

Name

Gity Ozgoli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment of effect of aromatherapy with essential oil of Peppermint and essential oil of Cloves on

pain intensity and anxiety in first stage of labor on primiparous women.

Public title

Comparative assessment of effect of aromatherapy with essential oil of Peppermint and essential oil of Cloves on pain intensity and anxiety in first stage of labor.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Nulliparus women of age 18 to 35 years; Gestational age between 38 to 42 week; single pregnancy with cephalic presentation; newborn weight between 2500 to 4000 gr; the onset of spontaneous contraction and dilatation 4,3 cm; body mass index ranging from 19.8 to 26; do not have allergy to Cloves; do not have allergy to Peppermint; the mother do not have use analgesic medication during intervention or 8 hours before intervention; the mother do not have problem with the smell; without having acute and chronic psycho social problem; non-smoking and drug abuse; without having medical disorder do not have pregnancy complications. Exclusion criteria: do not have awareness of the sensitivity of clove or peppermint; Peppermint or Clove allergy or intolerance; high blood pressure; heart disorders fetus; prolapse of the umbilical cord; placenta Abruption; delivery with devices or surgical; the patient have hidden anxiety, arrest in labor; emergency cesarean section before completing the study.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of

Medical Sciences

Street address

School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-05-04, 1393/02/14

Ethics committee reference number

11769

Health conditions studied

1

Description of health condition studied

Pain and anxiety in first stage of labor

ICD-10 code

O60-75

ICD-10 code description

Complications of labour and delivery

Primary outcomes

1

Description

intensity of pain in first stage of labor

Timepoint

Before intervention, three times after intervention in dilataions 4 to 5 cm, 6 to 7 cm, 8 to 10 cm

Method of measurement

Numerical Analogue Scale (ruler Pain)

2

Description

intensity of anxiety in first stage of labor

Timepoint

Before intervention, twice after intervention in dilatations of 3 to 4 cm, 8 to 10 cm

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

in the first group: 0.2 ml essential oil of Peppermint will be treated to gas and attached to dresses collar of women and essential every half hour will be repeated until end of delivery.

Category

Treatment - Drugs

2

Description

In second group: 0.2 mil essential oil of Cloves will be treated to gas and attached to dresses collar of women and essential every half hour will be repeated until end of delivery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kmali Hospital

Full name of responsible person

Shokofeh Torkashvand

Street address

Shohada square

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of School of Nursing and Midwifery of Shahid Beheshti University of Med

Full name of responsible person

Dr.Mahrokh Dolatian

Street address

School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran

City

Tehran

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 of School of Nursing and Midwifery of Shahid Beheshti University of Med

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Gity Ozgoli

Position

PHD of Reproductive Health /Supervisor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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

