Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 mil essential oil of Peppermint and in the second group, 0.2 mil essential oil of Cloves will 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

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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 Analouge Scale (ruler Pain)

2

Description
intensity of anxiety in first stage of labor
Timepoint
Before intervention, twice after intervention in dilatasions 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 mil essential oil of Peppermint will 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 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 /Superviser
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Email
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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

Data Dictionary	*empty*