Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of aromatherapy with essential oils cloves and Citrus Aurantium on pain and anxiety in the first stage of labor in primiparous women referring to Bam Pasteur Hospital

Protocol summary

Study aim

Comparison of aromatherapy with essential oils cloves and Citrus Aurantium on pain and anxiety in the first stage of labor in primiparous women referring to Bam Pasteur Hospital

Design

This clinical trial study will be recorded on the website of the Iranian clinical trial site and the Ethics Committee of the University. Thus, of the 135 primiparous women who are considered for research purposes, these numbers are randomly selected and allocated to treatment centers on a day-by-day basis.they will divid into three groups: clove (45) and Citrus Aurantium (45) and control group (45). To confirm people, three groups of weekly treatments will be used. Six cards of 6 days a week, called perfumes (two cards clove and two card cards Citrus Aurantium and two cards control groups) are prepared from the beginning of each week. A random card No selection choices and the selected fragrances are applied to women on that day. Before starting research, the personal, midwifery and anxiety questionnaire will be given to the individual and a description of how to answer the pain scale will be explained and the patient will be measured the pain before the onset . Therapeutic therapy will begin with a dilation of 3-4 cm. And for 20 minutes, the sensation of pain is measured. In the first group, 0.2 ml of cloves and in the second group, 4 ml of essential oil, and in the third group, 4 ml of normal saline, will be gassed and attached to the collar of the samples, and the essential oil will be repeated every half hour. The severity of pain will be measured in dilates of 3-4, 5-7 and 8-10 cm and the severity of anxiety will be measured at dilatation of 3-4 and 8-10 cm.

Settings and conduct

This study will be conducted at labour ward of Pastor Bam Hospital. Each morning, by choosing one of the cards, the selected fragrance is used.

Participants/Inclusion and exclusion criteria

primiparous, be Iranian, Pregnancy is 40-38 weeks, age 35 should be 18 years old, The gestational age is 42-37 weeks, according to the first half-degree ultrasound or LMP, Do not have a pelvic pain in the clinical examination, The estimated normal fetal weight is 2500 gr. 4000, The onset of contractions is spontaneous and at the beginning of the study should have a dilatation of 3-4 cm. The mother's BMI is 26-19.8, Do not have a history of allergy to clove and Citrus Aurantium on the basis of person's statements, It has not used narcotic about 8 hours before the active phase of labor, Lack of illness or complications of pregnancy There is no problem with smell. There is no known acute and chronic psychiatric neuropathy and currently does not receive any special psychosomatic medication. Do not have a history of alcohol and drug addiction. There is no indication of cesarean section, such as surgery on the uterus, placenta, preeclampsia and fetal distress.

Intervention groups

Study 3 groups. The first group of essential oils of cloves and the second group of Citrus Aurantium and one control group

Main outcome variables

The amount of anxiety; the severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171224038025N1**
Registration date: **2018-02-23, 1396/12/04**
Registration timing: **prospective**

Last update: **2018-02-23, 1396/12/04**
Update count: **0**

Registration date

2018-02-23, 1396/12/04

Registrant information

Name

Mahin Khajehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4421 7378

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of aromatherapy with essential oils cloves and Citrus Aurantium on pain and anxiety in the first stage of labor in primiparous women referring to Bam Pasteur Hospital

Public title

Comparison of aromatherapy with essential oils cloves and Citrus Aurantium on pain and anxiety in the first stage of labor in primiparous women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

primiparous

Exclusion criteria:

Age

From **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

To confirm people, three groups of weekly treatments will be used. Six cards of 6 days a week, called perfumes (two cards clove and two card cards Citrus Aurantium and two cards control groups) are prepared from the beginning of each week. A random card No selection choices and the selected fragrances are applied to women on that day

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 Bam University of Medical Sciences

Street address

persian gulf

City

Bam

Province

Kerman

Postal code

7661713669

Approval date

2017-12-21, 1396/09/30

Ethics committee reference number

Mubam.Rec.1396.55

Health conditions studied

1

Description of health condition studied

Pain and anxiety in the first stage of labor

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intensity of labor pain

Timepoint

The severity of pain in the first stage of labor is measured at dilates of 3-4, 5-7 and 8-10 cm

Method of measurement

Visual Analogue Scale

2

Description

The amount of labor anxiety

Timepoint
The amount of anxiety in the dilatation is 3-4 and 8-10 cm
Method of measurement
Spielberger Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first intervention group will consume 0.2 ml of cloves and clot in the collar of the specimens, and every half hour the corresponding essential oil will be repeated. The severity of pain will be measured in dilates of 3-4, 5-7 and 8-10 cm and the severity of anxiety will be measured at dilatation of 3-4 and 8-10 cm
Category
Other

2

Description
Intervention group: In the second intervention group, 4 ml of essential oil of Citrus Aurantium will be attached to the collar of the samples, and every half an hour the prescribed essential oil will be repeated. The severity of pain will be measured in dilates of 3-4, 5-7 and 8-10 cm and the severity of anxiety will be measured at dilatation of 3-4 and 8-10 cm.
Category
Other

3

Description
Control group: In the third group or control group, 4 ml of normal saline will be gassed and bonded to the collar of the samples, and each half an hour the prescribed essential oil will be repeated. The severity of pain will be measured in dilates of 3-4, 5-7 and 8-10 cm and the severity of anxiety will be measured at dilatation of 3-4 and 8-10 cm.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pasteur Hospital in Bam
Full name of responsible person
Mahin khajehpour
Street address
Persian Gulf Blvd
City
Bam
Province
Kerman
Postal code
7618716519
Phone
+98 34 4421 3929
Email
m.khajehpoor@mubam.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bam University of Medical Sciences
Full name of responsible person
Mohammad Reza Aflatoonian
Street address
Persian Gulf Blvd.
City
Bam
Province
Kerman
Postal code
7661713669
Phone
+98 34 4421 6180
Email
pazhoohesh@mubam.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bam University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Bam University of Medical Sciences
Full name of responsible person
Mahin khajehpour
Position
Instructor
Latest degree
Master

Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Mahin khajehpour
Position
Instructor
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
Mahin khajehpour
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data on the outcome of study (pain relief and delivery anxiety)
When the data will become available and for how long
After completion of the sampling all the consequences are presented in a report
To whom data/document is available
Head of Hospital and Research Deputy of Bam University of Medical Sciences
Under which criteria data/document could be used
After publishing an article in the internal journal, the results of the research will be provided to individuals upon request by email
From where data/document is obtainable
Author
What processes are involved for a request to access data/document
Applying from the email or through the university
Comments