Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Effect of Salvia Officinalis aroma on severity of Labor pain and anxiety

Protocol summary

Summary

This study is a single blind randomized clinical trial two-group that will do in order to effect of Salvia Officinalis aroma on Labor Pain and anxiety on 160 pregnant women who were referred to the Moatazedi hospital in Kermanshah. Inclusion criteria: gestational age 42-38 weeks; with a singleton live fetus and cephalic presentation; Examination of cervical dilatation on arrival 4-3 cm; without any medical problems or complications of pregnancy and mental illness. The exclusion criteria were: mother's unwillingness to continue to participate in the study; occurrence of any difficulties during the study. Before intervention Visual Analogue Scale and Spielberger scale were completed by both groups, pain and anxiety scores are determined. In the intervention group three drops of Salvia Officinalis fragrance were poured on a cotton and is connected to the cloths collar of samples and it repeated every half hour. The control group received aromatherapy via a similar method, using three drops of normal saline. After the intervention, anxiety in 5-7 dilatation and pain in dilatations of 3-4, 5-7 and 8-10 cm is measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042727633N1**
Registration date: **2016-05-15, 1395/02/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

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Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Assistance of research Kermanshah University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Salvia Officinalis aroma on severity of Labor pain and anxiety

Public title

Effect of Salvia Officinalis aroma on severity of Labor pain and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

nclusion criteria: gestational age 42-38 weeks; with a singleton live fetus and cephalic presentation and approved by ultrasound; Examination of cervical dilatation on arrival 4-3 cm; without any medical problems or complications of pregnancy and mental illness; lack of respiratory diseases and allergies; having tested positive smell; lack of drug addiction and alert in time and place. The exclusion criteria were: mother's

unwillingness to continue to participate in the study; occurrence of Any difficulties during the study(such as cord prolapse; placental abruption; preeclampsia , etc.); receive analgesic 3 hours before the intervention and decreaseof consciousness.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah University of Medical Sciences

Street address
Boulevard martyr Beheshti University of Medical Sciences Building Number One

City
Kermanshah

Postal code

Approval date
2015-10-20, 1394/07/28

Ethics committee reference number
KUMS.REC.1394.168

Health conditions studied

1

Description of health condition studied
Abdominal and pelvic pain

ICD-10 code
R10.3

ICD-10 code description
pain localized to other parts of lower abdomen

2

Description of health condition studied
Anxiety

ICD-10 code
f41.9

ICD-10 code description
anxiety disorder unspecified/anxiety NOS

Primary outcomes

1

Description
Anxiety

Timepoint
Before the intervention, and at 7-5 cm dilatation

Method of measurement
Scale (STAI)

2

Description
pain

Timepoint
Before the intervention and dilatations of 3-4, 5-7 and 8-10 cm

Method of measurement
VAS

Secondary outcomes

1

Description
Apgar of newborn

Timepoint
The first and fifth minutes after birth

Method of measurement
Scale five of determination of Apgar

2

Description
time of first Stage of Labor

Timepoint
In dilatation of 4-3, 7-5 and 10-8 cm

Method of measurement
duration and interval of conteractions, dilatation and effacement of cervix

Intervention groups

1

Description
In the intervention group three drops of Salvia Officinalis fragrance were poured on a cotton and is connected to the cloths collar of samples and it repeated every half hour

Category
Treatment - Drugs

2

Description
In the contorol group three drops of normalsalin were poured on a cotton and is connected to the cloths collar of samples and it repeated every half hour
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Moatazedi hospital in Kermanshah
Full name of responsible person
Frozan sharifipour
Street address
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Azam bakhteh
Street address
Dolat abad
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
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
Kermanshah University of Medical Sciences, School of Nursing and Midwifery
Full name of responsible person
Frozan sharifipour
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Person responsible for updating data

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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