

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Name

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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 conetractions, 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 control group three drops of normal saline were poured on a cotton and is connected to the cloth 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

Position

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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