Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of lavender aromatherapy on pentavallan vaccination

Protocol summary

Summary

The title of this study is"The effect of lavender aromatherapy on pain of pentavalent vaccination. Background and aim: It is well- known that the fetus and infant can respond to pain stimulus. Therefore, vaccination is a painful procedure in infants. Different methods like kangaroo care were applied to reduce vaccination pain in infants but, inhalation aromatherapy was considered less than other methods. The objective of this study is to assess effectiveness of inhalation aromatherapy on pain due to penatvalent vaccination in infants. Inclusion criteria included: parents' willingness to participate their infants; infants with term birth (37-42 weeks); healthy and without any congenital anomaly infants. Methods: in the centers for vaccination, infants who need to pentavalent vaccination are assigned to lavender group or control group (sweet almond oil group) randomly. Infants will be placed on vaccination bed and baseline pain assessment will fill out for them. Then, using a sterile 4 by 4 gauze pad with 3- 4 drops oil dripped on, inhalation aromatherapy will be started. Inhalation aromatherapy last 1 minute. Then, the vaccinator will inject the vaccine. Pain assessments will be done 15 seconds and 5 minutes after vaccination again. If the infant cannot tolerate the aromatherapy oils, the intervention will be discontinued immediately. This study is a double blind research. The research assistant that will collect the data are blind to materials of aromatherapy also. Furthermore, in this study 1% lavender oil will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072310327N14**
Registration date: **2016-08-03, 1395/05/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-03, 1395/05/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-06-09, 1395/03/20

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lavender aromatherapy on pentavallan vaccination

Public title

The effect of lavender aromatherapy on pain of pentavalent vaccination

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: parent's willingness to participate their

infants; infants with term birth (37-42 weeks); healthy infants; infants without any congenital anomaly.
exclusion criteria: Intolerance of inhalation of lavender oil or control substance during the study and infants with persistent crying before intervention

Age
From **2 months** old to **4 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand street

City
Shiraz

Postal code

Approval date
2016-03-06, 1394/12/16

Ethics committee reference number
IR.SUMS.REC.1394.204

Health conditions studied

1

Description of health condition studied
Pain due to vaccination

ICD-10 code
T79

ICD-10 code description
Certain early complications of trauma, not elsewhere classified

Primary outcomes

1

Description
Pain

Timepoint
Before, 15 seconds and 5 minutes after intervention

Method of measurement
Infants pain assessment scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: inhalation aromatherapy by 1% lavender oilwill be used, 3-4 drops in a 4 by 4 gauze pad from one minute before vaccination. this pad will be place next to infant's head.

Category
Prevention

2

Description
Control group: 3-4 drops of sweet almond as placebo will be used in this group.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Sadi Health Center

Full name of responsible person
Zahra Ghosropoor

Street address

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Basir Hashemi

Street address
Shiraz University of Medical Sciences, Zand street

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Shiraz

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

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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