Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Aromatherapy with Lavender Oil on Behavioral and Physiological Indices Infants Undergoing Vaccination in Comprehensive Health Center

Protocol summary

Study aim
Determining The Effect of Aromatherapy with Lavender Oil on Behavioral and Physiological Indices Infants Undergoing Vaccination

Design
A clinical trial with a sham and control group, with parallel groups, three-blind, randomized by permuted blocks, on 90 samples, Random allocatin software

Settings and conduct
The place of the study is Rasht Comprehensive Health Center No. 7. the participants, evaluator and Allocating the samples to the groups will be blinded. In the intervention group, five drops of Lavender oil will be poured on a cotton ball and placed at a distance of 3 cm from the infant's nose, and from 5 minutes before, during and 5 Minutes after Vaccination , the aromatherapy continues. Pain and physiological data will be evaluated 5 minutes before, during and 5 minutes after the injection.

Participants/Inclusion and exclusion criteria
Age 2 to 7 months, Being in the normal percentile of weight and height growth when receiving the vaccine, Being at term (38 to 42 weeks of pregnancy), Calm and not crying before receiving the vaccine, Temperature between36 to 37.2 degrees Celsius; Taking acetaminophen or any other pain reliever 3 hours before vaccination, Having a history of hospitalization, Suffering from diseases such as thyroid disorders, epilepsy, cardiovascular disease, and acute diseases . Having trouble sleeping or insomnia before the vaccine injection

Intervention groups
In the intervention group, Lavender oil will be placed on a cotton ball at a distance of 3 cm from the infant's nose, and aromatherapy will continue for 5 minutes before, during and 5 minutes after vaccination. Pain and physiological data are also measured at the same time. Distilled water will be used by the same protocol in the placebo group and the control group will not receive any additional intervention.

Main outcome variables
Pain level; Physiological indicators; Crying duration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221119056541N1**
Registration date: **2023-04-13, 1402/01/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-13, 1402/01/24**
Update count: **0**

Registration date
2023-04-13, 1402/01/24

Registrant information

Name
parichehr shahroudi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-06, 1402/01/17

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aromatherapy with Lavender Oil on Behavioral and Physiological Indices Infants Undergoing Vaccination in Comprehensive Health Center

Public title

The Effect of Aromatherapy with Lavender Oil on Behavioral and Physiological Indices

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 2 to 7 months Being in the normal percentile of weight and height growth when receiving the vaccine Term (38 to 42 weeks of pregnancy) to be calm and not crying the infant before receiving the vaccine The temperature is between36 to 37.2 degrees Celsius

Exclusion criteria:

Taking acetaminophen or any other pain reliever 3 hours before vaccination Having a history of hospitalization Suffering from diseases such as thyroid disorders, epilepsy and cardiovascular disease and acute diseases Having trouble sleeping or insomnia before the vaccine injection

Age

From **2 months** old to **7 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the samples that meet the criteria for entering the research will be selected as available, and then they will be randomly sampled using the permutation block method with blocks of six in the form of ABCABC. SO that the letter "C" will be considered as the control group, the letter "B" will be considered as the sham group and the letter "A" will be considered as the intervention group. The blocks will be registered and drawn in all possible situations. So that every time a lottery block is randomly selected and the obtained block is returned to the lottery container after registration. Sampling will continue until reaching the determined sample size in each group (30 people). To create a sequence after recording the different and possible states of placing three letters A, B and C in blocks of 6 and placing each letter in separate sheets, in the next step, the written papers are placed inside a container and using Randomly, every time one of the cards is removed from the said container and the letters are written on it in order and the desired card is returned to the container. The number of repetitions of the lottery will be determined after determining the number of the sample size, so that every time the letters on the sheet are removed, they will be added in the same order next to the previous letters. In the next step, sealed envelopes will be used for concealment. In this way, each of the determined letters is assigned a number equal to the determined sample volume, and the desired letter is placed inside an envelope and the number of that letter will be written on the envelope. The method of allocating the samples to each of the intervention, sham and control groups is that by choosing each infant who meets the criteria for entering the study, one of these envelopes is opened in the order of the number on the envelope and the letter inside the envelope is shown. to indicate which group that infant should be placed in.Random allocation software can also be used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the participants in the study who are infants are not aware of which group they are in (according to their age conditions) (of course, the parents of these children will be aware). Also, people who randomly assign groups and choose blocks A, B, and C for this purpose are not aware of which group each of the letters A, B, and C belongs to, and which group each person is in. Also, the person doing the analysis will not be aware of the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

In Front of 17 Shahrivar Hospital, Shahid Siyadati St, Namjo St,

City

Rasht

Province

Guilan

Postal code

4193893345

Approval date

2022-08-17, 1401/05/26

Ethics committee reference number
IR.GUMS.REC.1401.285

Health conditions studied

1

Description of health condition studied
Pain relief methods
ICD-10 code
Z40-Z54 Pe
ICD-10 code description
XXI Factors influencing health status and contact with health services

Primary outcomes

1

Description
Pain level
Timepoint
The pain level will be evaluated 5 minutes before, during and 5 minutes after the injection of the vaccine.
Method of measurement
Using the Face, Legs, Activity, Cry, Consolability scale (FLACC scale) , Which is a suitable tool for evaluating pain-related behaviors in children aged 2 months to 7 years. This scale has 5 parts and examines the level of pain through facial reactions, the way the legs are placed, the amount of mobility, crying and relaxation. A score of 0 to 2 is assigned to each of these sections, and finally the scores are added together. Based on the overall score, a score of zero means no pain and 10 means the most severe level of pain. The overall score is divided into three levels: a score of 0 to 3 indicates reduced pain, 4 to 7 indicates moderate pain, and 7 to 10 means severe pain.

Secondary outcomes

1

Description
Physiological indices
Timepoint
Physiological indices (respiration rate, heart rate and arterial oxygen saturation percentage) will be evaluated by pulse oximetry device, 5 minutes before, during and 5 minutes after the vaccine injection
Method of measurement
In order to measure the physiological indicators (arterial blood oxygen saturation level, heart rate), a children's finger pulse oximeter device of Zylux Med brand with code CMS 50 QB made in China will be used. To measure the breathing rate, the researcher will help after vision The videos record the number of breaths

2

Description
Duration of crying
Timepoint
At the same time as the needle enters the skin, the sound of the infant's cry is recorded. The criterion for the beginning and end of crying is based on the definition of the first cry from the first audible sound to the first pause that lasts at least five seconds
Method of measurement
Galaxy J7 Pro model SM-J730F chronometer will be used to measure the duration of infant crying.

Intervention groups

1

Description
Intervention group1: The condition of light, lighting and temperature of the environment is the same for all infants. At the beginning of data collection, all the infants are awake, without crying and in calm conditions.Their diapers are dry and they have not received any food, including milk or other sweets, at least 30 minutes before the start of vaccination.In the condition that the infant is in a calm state, the researcher fixed the finger pulse oximeter on the infant's toe by means of a piece of hypoallergenic adhesive without creating additional pressure, and then 5 minutes before the start of the vaccination, the responses were not given. Grading is done from the beginning to the end of the procedure. This work is done by the observer from the beginning to the end of the vaccination. shaking and any other actions will be avoided during the entire intervention period. At the same time as the needle enters the skin, the sound of the infant's cry is recorded.The criterion for the beginning and end of crying is based on the definition of the first cry from the first audible sound to the first pause that lasts at least five seconds. On the one hand, after the needle is fully inserted into the skin, the number of heart beats per minute, the oxygen saturation percentage of the arterial blood, and the breathing rate are recorded again.During the entire duration of vaccination, the cotton will be kept without close contact with the baby's nose. According to the purpose of the research, the data collection tools include a demographic questionnaire, a pain checklist, a pulse oximetry device, and a Chronometer device . Lavender oil will be procured from Sobhan Pharmaceutical Company.In previous studies, different concentrations of lavender oil, up to 10%, were used during infancy and no serious side effects were reported.We will use 5 drops of 5% concentration. A research assistant is trained to implement the study protocol. He is not informed about the contents of the dishes. In the lavender group, the infants are placed in the vaccination bed 5 minutes before the intervention, the intensity of the basic pain is determined 5 minutes before the intervention, and then lavender oil inhalation will begin.Five drops of lavender oil are poured on a cotton ball and placed at a distance of 3 cm from the infant's nose, and the aromatherapy continues from 5 minutes before the intervention, during the intervention and 5 minutes after that, then the vaccine is injected. A skilled nurse administered all pentavalent vaccines during our study.Pain will be

assessed 5 minutes before, during and 5 minutes after the injection. Video recording of the procedure is done for all infants and is reviewed at the right time. Physiological data (respiration rate, heart rate and percentage of arterial oxygen saturation) are evaluated by pulse oximetry device, 5 minutes before, during and 5 minutes after the injection. The number of breaths is also recorded by the assistant researcher after watching the videos.

Category

Prevention

2

Description

Intervention group2: The condition of light, lighting and temperature of the environment is the same for all infants. At the beginning of data collection, all the infants are awake, without crying and in calm conditions.Their diapers are dry and they have not received any food, including milk or other sweets, at least 30 minutes before the start of vaccination.In the condition that the infant is in a calm state, the researcher fixed the finger pulse oximeter on the infant's toe by means of a piece of hypoallergenic adhesive without creating additional pressure, and then 5 minutes before the start of the vaccination, the responses were not given. Grading is done from the beginning to the end of the procedure. This work is done by the observer from the beginning to the end of the vaccination. shaking and any other actions will be avoided during the entire intervention period. At the same time as the needle enters the skin, the sound of the infant's cry is recorded.The criterion for the beginning and end of crying is based on the definition of the first cry from the first audible sound to the first pause that lasts at least five seconds. On the one hand, after the needle is fully inserted into the skin, the number of heart beats per minute, the oxygen saturation percentage of the arterial blood, and the breathing rate are recorded again.During the entire duration of vaccination, the cotton will be kept without close contact with the baby's nose. According to the purpose of the research, the data collection tools include a demographic questionnaire, a pain checklist, a pulse oximetry device, and a Chronometer device.In this study, distilled water will be used as a placebo. Both placebo and lavender oil are prepared in the same containers. A research assistant is trained to implement the study protocol. He is not informed about the contents of the dishes. In the distilled water group, infants are placed on the vaccination bed 5 minutes before the intervention, the intensity of the basic pain is determined 5 minutes before the intervention, and then the inhalation of distilled water will begin. Five drops of distilled water are poured on a cotton ball and placed at a distance of 3 cm from the infant's nose, and the aromatherapy continues 5 minutes before the intervention, during the intervention and 5 minutes after that, and then the vaccine is injected. A skilled nurse administered all pentavalent vaccines during our study. Pain will be assessed 5 minutes before, during and 5 minutes after the injection. Video recording of the procedure is done for all infants and is reviewed at the right time. Physiological data (respiration rate, heart rate and percentage of arterial oxygen saturation) are evaluated by pulse oximetry device, 5 minutes before, during and 5 minutes after the injection. The number of breaths is also recorded by the assistant researcher after watching the videos.

Category

Placebo

3

Description

Control group: They will not receive any additional intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Center No. 8, Rasht

Full name of responsible person

Parichehr shahroudi

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18 Khazar Alley, Khazar Street, Lahijan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Parichehr Shahroudi
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Master
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of data
Study Protocol
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The research report will be sent to deputy of research and technology of Guilan University of Medical Sciences
When the data will become available and for how long
Around June 1402
To whom data/document is available

Health Center managers and relevant policymakers

Under which criteria data/document could be used

Descriptive analysis

From where data/document is obtainable

Deputy of research and technology of Guilan University of Medical Sciences

What processes are involved for a request to access data/document

To deputy of research and technology of Guilan University of Medical Sciences

Comments