Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of aromatherapy with rose water and breast milk on physiological responses and pain due to pentavalan injection in infants

Protocol summary

Study aim

Evaluation of the effect of aromatherapy with rose and breast milk on physiological responses and pain caused by injection of the pentavalent vaccine in 2-month-old infants

Design

Randomized clinical trial using a randomized, three-way, randomized, and three-blind, randomized, three-blind, randomized, three-blind, randomized, three-blind, three-blind, three-blind, three-blind, three-blind, three-blind, three-blind, three-blind; To three groups of 75 people

Settings and conduct

In the group of breast milk and rose (1 minute before vaccination with cotton balls containing 5 drops of each fragrance) is done. The cotton balls will be placed on the upper part of the infant's clothing, at a distance of 3 cm from the infant's nose, and aromatherapy will continue during vaccination. In the control group, odorless cotton balls will be used for the infant until the end of the injection and in the mother's arms. The vaccine will be injected intramuscularly by an experienced and experienced person who is proficient in injecting the vaccine into the middle lateral third of the infant thigh muscle. The injection site, syringe type, vaccine volume, injection technique and angle, and the position of the infant in the mother's arms will be the same for everyone.The results will then be analyzed using recorded videos and MBPS tools and physiological responses.

Participants/Inclusion and exclusion criteria

Complete parental satisfaction - 2-month-old infants - Calmness and alertness of infants before vaccination-Dry diapers - No congenital anomalies, colds or diarrhea-breastfeeding

Intervention groups

Aromatherapy group with breast milk, rose and control group

Main outcome variables

Study groups; Infants heart rate; SPO2 infants; Pain score; Duration of crying

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210630051747N1**
Registration date: **2021-12-28, 1400/10/07**
Registration timing: **retrospective**

Last update: **2021-12-28, 1400/10/07**
Update count: **0**

Registration date

2021-12-28, 1400/10/07

Registrant information

Name

Nasrin Baharvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3343 4383

Email address

nasriiiinbaharvand@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-20, 1400/04/29

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of aromatherapy with rose water and breast milk on physiological responses and pain due to pentavalan injection in infants

Public title
The effect of aromatherapy on pain in 2-month-old infants

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Have the full and informed consent of the parents Infants are 2 months old The infant should be calm and alert before starting the vaccination. Dry baby diapers The infant does not have a congenital anomaly The baby does not have a cold or diarrhea The infant should be exclusively breastfeed

Exclusion criteria:
Any problems in injecting the pentavalent vaccine (repeat injection, selection of inappropriate site, injection angle, injection depth, wrong choice, vaccine type, vaccine volume) There should be crying and restlessness 5 seconds before the start of the vaccination Skin and respiratory allergy symptoms occur during the intervention Have a history of surgery or hospitalization Take painkillers or sedatives for 24 hours before vaccination by the child or mother The mother is sensitive to different odors The mother has asthma Use systematic analgesics such as ibuprofen and acetaminophen before vaccination Infant who a restless mother or parent or are faced witth the question of whether they are stressed or anxious they answer in the affrimative

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **225**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be selected based on the inclusion criteria, then using a table of randomly prepared blocks, we will divide the infants into three groups under aromatherapy with breast milk, rose water and control.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The 2-month-old infants in our study population will naturally be unaware of what is going on around them. Pain assessors who assess infants 'pain through recorded videos, as well as data analysts and data safety and monitoring committees, are unaware of infants' allocation to study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
سامانه مدیریت اطلاعاتی پژوهشیار

Street address
Goldasht Sharghi - in front of the courthouse, Ebony II alley

City
Khoraamaàbad

Province
Lorestan

Postal code
6819745669

Approval date
2021-03-10, 1399/12/20

Ethics committee reference number
IR.LUMS.REC.1399.360

Health conditions studied

1

Description of health condition studied
Pain, infancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain score

Timepoint
before, during and after the intervention

Method of measurement
MBPS scale

Secondary outcomes

1

Description
Physiological responses

Timepoint
before, during and after the intervention
Method of measurement
Pulse oximetry

Intervention groups

1

Description
Aromatherapy with breast milk for 3 minutes, before, during and after the interventio
Category
Prevention

2

Description
Aromatherapy with rose water for 3 minutes, before, during and after the intervention
Category
Prevention

3

Description
Control group: No aromatherapy
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
مرکز جامع خدمات سلامت
Full name of responsible person
نسرین بهاروند
Street address
Goldasht Gharbi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Ebrahim Fallahi
Street address
Pardis building, 4km of Boroujerd_Khorramabad road, Kamalvand
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Province
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Postal code
6814993165
Phone
+98 66 3330 0661
Email
research@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Nasrin Baharvand
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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