

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of aromatherapy with rose water and breast milk on physiological responses and pain due to pentavalent 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; 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

nasriibaharvand@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 pentavalent 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 breastfed

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 with the question of whether they are stressed or anxious they answer in the affirmative

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 پژوهشیاری

Street address

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

City

Khoraamaabad

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 intervention

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

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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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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

Contact

Name of organization / entity

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Full name of responsible person

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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

Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

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Position

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