Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Lavender and Rose Aromas on Vaccination Pain in 2-Month-Old Infants: A Randomized Triple-Blind Clinical Trial

Protocol summary

Study aim

Comparison of the Effects of Lavender and Rose Aromas on Vaccination Pain

Design

This is a parallel group, controlled clinical trial with triple blinding, conducted on 75 children. The rand function in Excel is used for randomization.

Settings and conduct

Target Population: All healthy two-month-old children visiting vaccination centers in Jahrom. Sampling Framework: The list of visitors during the sampling period is used, and samples are selected using random block sampling. In each six-person block, two children are allocated to different groups (lavender, rose essence, and control group). Allocation is carried out by an independent researcher using Excel, and after confirming inclusion criteria and obtaining consent, children are assigned to their respective groups. Blinding: The study is conducted as triple-blind, ensuring that participants, outcome assessors, and data analysts are unaware of group allocations, which reduces the risk of bias.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Age of children: 2 months to 2 months and 29 days. 2. Only healthy children. 3. Suitable weight and general condition for vaccination. 4. Informed consent from parents/legal guardians. 5. No systemic diseases. 6. No hospital admission history. 7. No known allergies to essences or herbal oils. 8. No bleeding or hematological disorders. Exclusion Criteria: 1. Occurrence of any unusual vaccine-related adverse effects. 2. Skin or subcutaneous tissue problems making vaccination difficult. 3. Use of painkillers/sedatives 24 hours before vaccination. 4. Any allergic reactions or severe restlessness before intervention.

Intervention groups

1.Lavender Aroma Inhalation Group 2.Geranium Aroma Inhalation Group 3.Control Group

Main outcome variables

Pain relief from vaccination.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260224068930N1**
Registration date: **2026-04-29, 1405/02/09**
Registration timing: **prospective**

Last update: **2026-04-29, 1405/02/09**
Update count: **0**

Registration date

2026-04-29, 1405/02/09

Registrant information

Name

Fatemeh Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5434 0405

Email address

f.nazari@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-06-22, 1405/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Lavender and Rose Aromas on Vaccination Pain in 2-Month-Old Infants: A Randomized Triple-Blind Clinical Trial

Public title

Comparison of the Effects of Lavender and Rose Aromas on Vaccination Pain

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 2 months to 2 months and 29 days. Only healthy children (without any illness or symptoms such as fever, runny nose, diarrhea, etc.) Children with suitable weight and general condition for vaccination. Parents/legal guardians must sign an informed consent form. Children who do not have systemic diseases (such as diabetes, vascular diseases, congenital anomalies, etc.). Children with no history of hospitalization for any reason (as hospitalization has long been recognized as a painful experience that may affect children's outcomes). No known allergies to essential oils or herbal oils. No bleeding disorders or hematological conditions (as these disorders may cause bleeding post-injection and complicate the situation, interfering with the assessment of the desired outcome).

Exclusion criteria:

Occurrence of any unusual and observable adverse events related to the vaccine injection, including active bleeding, trauma, bruising, or hematoma, which should be recorded in the "Intervention Cessation or Possible Adverse Effects" section of the researcher's data collection form. Children for whom vaccination may be difficult due to any skin or subcutaneous tissue problems (such as old hematomas, skin infections, etc.). Any use of analgesic/sedative medications within 24 hours prior to vaccination. Occurrence of an allergic reaction or severe restlessness prior to the intervention.

Age

From **2 months** old to **89 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Target Population: All healthy two-month-old children who visit selected vaccination centers in Jahrom for their periodic vaccinations. Sampling Framework: The list of visitors to the vaccination center during the sampling period (designated shifts) will be considered as the framework, and samples will be selected from eligible visitors according to the established method. To maintain a balance in the number of individuals in each group, a block randomization method with block sizes of six will be used. In this method, for each block of six individuals, the sequence of group assignments will be determined randomly, ensuring that in each block, two children are assigned to the inhalation group of lavender essential oil, two to the inhalation group of rose essential oil, and two to the control group (distilled water). The random sequence for group assignment for each block will be generated by an independent researcher who does not play a role in the recruitment process, intervention implementation, or data collection, using Excel software. Then, each participant's assignment will be placed separately in opaque, sealed, and consecutively numbered envelopes (the block assignments are presented in the table below the text). Upon each participant's entry into the study, after confirming the inclusion criteria and obtaining informed consent from the parents, the researcher responsible for recording and enrolling participants will sequentially open the envelopes according to their numbers, and each child will be placed into one of the three study groups based on the group indicated on the envelope. Since the individual preparing the envelopes is different from the one opening them, and the outcome assessor is unaware of the group assignments, allocation concealment and blinding are maintained, thus reducing the likelihood of bias in the allocation process and the evaluation of results.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be conducted as a triple-blind trial. Given that the participants are two-month-old infants, blinding at the participant level is inherently established. Furthermore, the outcome assessor (pain intensity) and data analyst will remain unaware of the group assignments. The allocation process will also be conducted in a blinded manner using opaque and sealed envelopes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of Jahrom University of Medical Sciences

Street address

Jahrom, at the end of Shahid Beheshti Boulevard, Office of the President and Vice Chancellor for Development of Jahrom University of Medical

Sciences.

City
Jahrom

Province
Fars

Postal code
7414846199

Approval date
2026-02-17, 1404/11/28

Ethics committee reference number
IR.JUMS.REC.1404.158

Health conditions studied

1

Description of health condition studied
Pain sensation during vaccination.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain score measurement based on the NIPS questionnaire.

Timepoint
1 minute before the intervention, during the intervention, 2 minutes after the intervention.

Method of measurement
NIPS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Inhalation with lavender aroma involves diluting one drop of 100% pure lavender essential oil with four drops of distilled water, which is then placed on a piece of sterile cotton. The standard medicinal lavender essential oil is produced by Barij Essence Pharmaceutical Company, Mashhad Ardehal, Kashan, Iran. The cotton is positioned approximately two centimeters from the baby's nose, and inhalation continues from 5 minutes before to 2 minutes after vaccination, being performed once for each child.

Category
Other

2

Description
Intervention group 2: Inhalation with the aroma of Rosa damascena involves moistening a piece of sterile cotton with two drops of 10% essential oil. The standard essential oil of rose is produced by Barij Essence Pharmaceutical Company, Mashhad Ardehal, Kashan, Iran. The cotton is positioned approximately two centimeters from the baby's nose, and inhalation continues from 5 minutes before to 2 minutes after vaccination, being performed once for each child.

Category
Other

3

Description
Control group: In the control group, a piece of cotton soaked in distilled water is placed approximately two centimeters from the baby's nose, and inhalation continues from 5 minutes before to 2 minutes after vaccination, being performed once for each child.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza (AS) Clinic (No. 6)

Full name of responsible person
Fatemeh Nazari

Street address
Manouchehri St., Farhang Square, Kalavan, Jahrom

City
Jahrom

Province
Fars

Postal code
7417753161

Phone
+98 71 5423 4611

Email
F.nazari@jums.ac.ir

2

Recruitment center

Name of recruitment center
Valiasr Clinic No. 1

Full name of responsible person
Fatemeh Nazari

Street address
Molavi St., Motahari Boulevard, Koshkak, Jahrom.

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 5444 6992

Email
F.nazari@jums.ac.ir

3

Recruitment center

Name of recruitment center
Fatemieh (S) Urban Comprehensive Health Services Center (Nik Eghbal)

Full name of responsible person
Fatemeh Nazari

Street address
Farhang shahr, Fatemieh (S) Urban Comprehensive Health Services Center (Nik Eghbal)

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 5444 6992

Email
F.Nazari@jums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Dr. Hosein Kargar Jahromi

Street address
Vice Chancellor for Research and Technology - Pardis Site - Jahrom University of Medical Sciences - Motahari Street - Jahrom

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 5444 0821

Email
h.kargar@jums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Jahrom 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
Jahrom University of Medical Sciences

Full name of responsible person
Fatemeh Nazari

Position
Academic Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Motahhari Street - Pardis Site - Jahrom University of Medical Sciences - Faculty of Nursing - Jahrom

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 5447 5601

Email
F.Nazari@jums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Fatemeh Nazari

Position
Academic Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Motahhari Street - Pardis Site - ahrom University of Medical Sciences - Faculty of Nursing - Jahrom

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 5447 5601

Email
F.Nazari@jums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Fatemeh Nazari

Position
Academic Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Motahhari Street - Pardis Site - ahrom University of Medical Sciences - Faculty of Nursing - Jahrom
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5447 5601
Email
F.Nazari@jums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic information of the participants and pain scores based on the questionnaire will be released after anonymization. However, videos will only be shared if necessary and with the informed consent of the parents.
When the data will become available and for how long
Access period begins 6 months after the publication of the results
To whom data/document is available
Data is typically made available to researchers, universities, and organizations related to the research field. This includes students, researchers, and other interested parties. Additionally, many scientific journals request raw data for publication to verify the transparency and accuracy of the results.
Under which criteria data/document could be used
1. Clear Purpose: Applicants must state a clear purpose for using the data or documents. This purpose should align with research, educational, or social objectives. 2. Permitted Analyses: Analyses permitted on the data include statistical analyses, data modeling, and other non-destructive research methods. Any analysis must be conducted in a way that preserves the privacy and anonymity of individuals. 3. Permitted Uses of Documents: The use of documents is allowed for generating scientific and research results, presenting papers, or educational projects. Any commercial or non-scientific use is prohibited. 4. Legal Frameworks: Applicants must comply with legal and ethical requirements regarding privacy protection and data security. This includes signing confidentiality agreements and not disclosing information to third parties. 5. Requirements for Submitting Requests: -Provide identification information including name, title, and affiliated organization. -Clearly state the type of data or documents needed for access. -Provide a scientific justification for the need for access to the data or documents. -Confirm that the applicant agrees to the terms of use for the data and documents.
From where data/document is obtainable
Applicants should follow the methods below to request data/documents: Email: F.Nazari@jums.ac.ir; Liliom75.af@gmail.com Contact Numbers: 00989172233032; 00989368412261 Postal Address: Iran - Fars - Jahrom - Jahrom University of Medical Sciences - Nursing School - First Floor Fatemeh Nazari - Faculty Member Office Phone: 00987154340405-10; Extension 385
What processes are involved for a request to access data/document
1. Submitting the Request: The applicant must first submit their request via email or the contact numbers provided in the notice. At this stage, it is essential for the applicant to provide their complete details, the type of documents or data files required, and the purpose of the request. 2. Reviewing the Request: After receiving the request, the relevant team will review it. This stage may take up to 3 business days. If additional information is needed, the applicant may be contacted. 3. Approval and Preparation: If the request is approved, the process of gathering and preparing the documents or data files will begin. The duration of this stage may take between 5 to 10 business days, depending on the type and volume of the request. 4. Sending the Documents: Once prepared, the documents or data files will be sent to the applicant via email, or if a postal delivery is requested, they will be sent to the specified address. Postal delivery may take longer, usually between 5 to 15 business days. In total, the applicant can expect the entire process from submitting the request to receiving the documents to take about 2 to 4 weeks. If any delays occur during this period, the applicant can follow up by contacting the provided numbers.
Comments