Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of aromatherapy with lavender essence on pain and anxiety caused by intravenous catheter insertion in school-age children: A double-blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of aromatherapy with lavender essence on pain and anxiety caused by peripheral venous cannula placement in school-age children

Design

A randomized, double-blind, randomized controlled clinical trial on 96 patients was used to randomize the Excel software rand function.

Settings and conduct

venipuncture of children is performed in the emergency department of Amirkola Children's Hospital in the north of Iran. In the intervention group, five drops of natural lavender essential oil with a concentration of 2% and in the control group, 5 drops of distilled water are poured on a 4 in 4 gas.The child is asked to hold the gas in front of her/his nose for 5 minutes before the venipuncture In both groups, pain and anxiety is measured by the assessor immediately, five and ten minutes after the end of the venipuncture. All venipunctures is performed through the peripheral vein by a fixed nurse using cannula number 22.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children of school age between 6 and 12 years pain intensity score up to three Exclusion criteria: chronic diseases odor and perfume allergies sedatives and analgesics

Intervention groups

In the intervention group, five drops of lavender essence with a concentration of 2% are poured on a 4 in 4 gas and the child is asked to hold the gas and inhale it for five minutes before vein puncture. In the control group (distilled water), five drops of distilled water are poured on a 4 in 4 gas and the child is asked to hold the gas and inhale it for five minutes before vein puncture.

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042617N1**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name

Parvin Aziznejadroshan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-28, 1399/09/08

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of aromatherapy with lavender essence on pain and anxiety caused by intravenous catheter insertion in school-age children:A double-blind randomized clinical trial

Public title
The effect of aromatherapy with lavender essence on pain and anxiety in children
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children of school age between 6-12 years Ability to communicate First hospitalization experience Pain intensity score maximum 3
Exclusion criteria:
Chronic diseases History of asthma, allergies, dermatitis and allergies to fragrances Psychological illness
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Random sampling and allocation will be done by block statistical method using a randomization site by a statistical colleague. Thus, 96 eligible children will be equally and randomly divided into one of two groups (intervention and control). A random allocation list will be generated based on quadruple blocks. To hide random allocation, a list generated by a statistician is used. The group assigned to each person has a special code that is a combination of numbers and letters and does not have a specific order. After sampling, the individuals are assigned to the groups in the order of the allocation list in the hands of the statistician.We will use sealedenvelop online software to generate random sequences. There are 4 blocks (permutations of two A and two B) and 24 blocks are randomly selected by the site, which will produce a total of 96 samples.
Blinding (investigator's opinion)
Double blinded
Blinding description
Lavender essence and distilled water (placebo group) are poured into two similar glass containers. One person pours the essence oils onto a 4-by-4 gas and delivers it to another nurse (who is also blind to the drops used). The child is asked to hold the gas in front of her/his nose and inhale it for five minutes before the venipuncture. Outcome assessment is performed by another trained nurse who is not present in the room at the time of the intervention and is not aware of the type of intervention
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences
Street address
Gangafrose
City
Babol
Province
Mazandaran
Postal code
47176-47745
Approval date
2020-10-18, 1399/07/27
Ethics committee reference number
IR.MUBABOL.REC.1399.330

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
Z51.5
ICD-10 code description
Encounter for palliative care

2

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Pain scores
Timepoint
Immediately, five minutes and ten minutes after venipuncture
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Anxiety score
Timepoint
Immediately, five, ten minutes after venipuncture
Method of measurement
Observational Scale of Behavioral Distress- Revised

Intervention groups

1

Description
Intervention group: In the intervention group, five drops of natural lavender essential oil with a concentration of 2% (from Pars Pharmaceutical Idea Company) are poured on a 4 in 4 gas and the child is asked to hold the gas in front of his nose and inhale it for five minutes before venipuncture
Category
Treatment - Drugs

2

Description
Control group: In the control group, five drops distilled water are poured on a 4 in 4 gas and the child is asked to hold the gas in front of his nose and inhale it for five minutes before venipuncture
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola Children's Hospital
Full name of responsible person
Hassan Mahmoudi
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Imam Khomeini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
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Web page address
http://research.mubabol.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
50
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
Babol University of Medical Sciences
Full name of responsible person
Parvin Aziznejadroshan
Position
Faculty member
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Person responsible for updating data

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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
With the official consent of the Research Deputy of Babol University of Medical Sciences
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available