

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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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+98 11 3219 0597

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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 sealed envelope 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**

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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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Sponsors / Funding sources

1

Sponsor

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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

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

Latest degree

Ph.D.

Other areas of specialty/work

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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