

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the Effect of Aromatherapy and Distraction on the Pain Caused by Venipuncture in Hospitalized Children

Protocol summary

Study aim

Evaluation and comparison of the effect of aromatherapy and distraction on the Pain Caused by Venipuncture in children admitted to the pediatric ward of Ali ebne Abitaleb Hospital in Zahedan in 1398

Design

Clinical trial with two control groups and one intervention group, community-based and pragmatic, with parallel groups without blinding, randomized, on 90 patients, permutation of permutation modes A, 2 and 3 is used for randomization.

Settings and conduct

Children aged 3-8 years admitted to the pediatric ward of Ali ebne Abitaleb Hospital are randomly divided into three groups (two intervention groups and a control group). In the distraction group, the researcher uses a red hat puppet to talk and play with the child 3 minutes before the venipuncture begins (puppetry). In the aromatherapy group, the child inhales a handkerchief soaked in lavender essential oil attached to the collar of his shirt 20 minutes before the start of the vein. In the control group, only the severity of the child's pain after venipuncture was measured and no intervention was performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 3 to 8 years Family and child consent to participate in the study Non-Inclusion criteria: Children with asthma or allergies to aromatherapy Suffering from mental retardation Take painkillers before venipuncture Inability to communicate or lack of full consciousness

Intervention groups

In the distraction group, the researcher moves the red hat with the doll's hand and speaks and plays with the child in the language of the doll. In the aromatherapy group, the child inhales the lavender essential oil poured on a napkin attached to the collar of his shirt. In the control group, only pain was measured and no intervention was performed.

Main outcome variables

The amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041960N2**

Registration date: **2020-09-20, 1399/06/30**

Registration timing: **retrospective**

Last update: **2020-09-20, 1399/06/30**

Update count: **0**

Registration date

2020-09-20, 1399/06/30

Registrant information

Name

Fateme Avizhgan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4487 3295

Email address

avizhgan_f@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Aromatherapy and Distraction on the Pain Caused by Venipuncture in Hospitalized Children

Public title

Comparison of the effect of aromatherapy and distraction on pediatric venipuncture pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 3 to 8 years Family and child consent to participate in the study

Exclusion criteria:

Children with asthma or allergies to aromatherapy Suffering from mental retardation Receive painkillers before venipuncture Inability to communicate or lack of full consciousness

Age

From **3 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples with non-probability method available (easy) are selected from the pediatric ward of Ali Ibn Abitaleb Hospital in 1398 and meet the inclusion criteria. The samples are also assigned to the groups by permutation-class randomization method so that in addition to randomization of individuals between groups, they are also matched in terms of gender and age. There are three groups in this intervention. One control group, 2 aromatherapy groups and 3 doll groups. There are 6 permutations for numbers 1 to 3. Each case is assigned a number from 1 to 6, and by using the lottery until the sample size is completed, different permutation modes are selected and classified into groups based on being a boy or a girl and age under 5 years or over 5 years.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences and Health Services

Street address

Zahedan University of Medical Sciences, Janat Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-05-27, 1398/03/06

Ethics committee reference number

IR.ZAUMS.REC.1398.092

Health conditions studied**1****Description of health condition studied**

Pain after venipuncture

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain

Timepoint

10 minutes after venipuncture

Method of measurement

Pediatric Pain Inventory Scale, Ouscher Self Report Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Diverting using a red hat doll, the intervention will be performed for 3 minutes before the venous catheter is placed in the venipuncture room, and the distraction will continue until the end of the venous catheter placement, so that the researcher with the doll's hand Move the red hat and talk to the child in the language of the doll and play with him (puppetry).

Category

Other

2

Description

Intervention group 2: Aromatherapy with lavender, in this method, children for 20 minutes, 5 drops of 2% lavender essential oil prepared by Barij Essential Oil Pharmaceutical Company with ISO 9001 quality certificate and ISO / IEC 117025 standard poured on a 10 * 10 napkin They inhale the straps attached to the collar of their shirts and are then transported to a venipuncture room.

Category

Other

3

Description

Control group: In the control group, only pain was measured 10 minutes after venipuncture and no distraction and aromatherapy were performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Abne Abitaleb Hospital affiliated to Zahedan University of Medical Sciences and Health Services

Full name of responsible person

Shiva Karimi Afshar

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Zahedan University of Medical Sciences, Janat Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Normohammad Bakhshany

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Grant name

Grant code / Reference number

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

No

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Shiva Karimi Afshar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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

There is no more information.

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