Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Effect of inhalation aromatherapy with lavender essence versus placebo on physiological indicators and intensity of venipuncture pain in hospitalized preschool children in pediatric unit: a single blinded non randomized clinical trial

Protocol summary

Summary

Objective: effect of inhalation aromatherapy with lavender essence on physiological indicators and intensity of venipuncture pain in hospitalized preschool children in pediatric unit. Design: single blinded non randomized clinical trial. Setting and conduct: the children with following criteria will be enrolled into the study; a) Age 3 to 6 years; b) Having normal children's mental, verbal, visual and auditory abilities; c) Absence of any acute or chronic pain before venipuncture; d) Absence of diseases such as asthma, allergies, dermatitis and rhinitis according to the discretion of the physician. Exclusion criteria included: a) Incidence any kind of allergy to lavender essence during aromatherapy according to the discretion of the physician; b) Existence any problem to continue participating in the study. Intervention1: the physiological indicators of children will be measured in half an hour before entering into the venipuncture room and the children inhale 5 drops of lavender essence 2% which was poured onto 10×10 cm gauze attached to collar of children shirt in 20 minutes. Then, physiological indicators will be measured immediately after fixation of catheter and in minutes of 5 and 10 after exiting of venipuncture room. Intensity of pain will be measured in times of immediately, 5 and 10 after exiting of venipuncture room. Intervention2: The physiological indicators of children will be measured in half an hour before entering into the venipuncture room and the children inhale 5 drops of distilled water (placebo) which was poured onto 10×10 cm gauze attached to collar of children shirt in 20 minutes. Then, physiological indicators will be measured immediately after fixation of catheter and in minutes of 5 and 10 after exiting of venipuncture room. Intensity of pain will be measured in times of immediately, 5 and 10 after exiting of venipuncture room. Blinding: both lavender essence and distilled water (placebo) are prepared in dark and similar containers so children will not be aware of the kind of inhaler. Main outcome measures: heart rate and percent of arterial oxygen saturation will be measured by pulse-oximetry, respiratory rate by counting in one minute. Intensity of pain will be measured by Oucher pain scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503089759N6**
Registration date: **2015-06-14, 1394/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-14, 1394/03/24

Registrant information

Name

Ali Bikmoradi

Name of organization / entity

Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date
2015-04-30, 1394/02/10
Expected recruitment end date
2015-07-01, 1394/04/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of inhalation aromatherapy with lavender essence versus placebo on physiological indicators and intensity of venipuncture pain in hospitalized preschool children in pediatric unit: a single blinded non randomized clinical trial

Public title
Effect of aromatherapy on physiological indicators and intensity of pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion Criteria: a) Age 3 to 6 years; b) Having normal children's mental, verbal, visual and auditory abilities; c) Absence of any acute or chronic pain before venipuncture; d) Absence of diseases such as asthma, allergies, dermatitis and rhinitis according to the discretion of the physician. Exclusion criteria: a) Incidence any kind of allergy to lavender essence during aromatherapy according to the discretion of the physician; b) Existence any problem to continue participating in the study.
Age
From **3 years** old to **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Sampling is conventional and eligible children to enter the study in two separate stages on two experimental and control groups will be entered in the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamadan
City
Hamadan
Postal code
6517838678
Approval date
2015-04-11, 1394/01/22
Ethics committee reference number
UMSHA.REC.1394,20

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
R52.9
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Physiological indicators (heart rate, percent of arterial oxygen saturation, respiratory rate)
Timepoint
30 min before entering into the venipuncture room, immediately after fixation of catheter and 5 and 10 minutes after leaving the venipuncture room.
Method of measurement
Heart rate and percent of arterial oxygen saturation will be measured by pulse oximetry, respiratory rate by count researcher in one minute

Secondary outcomes

1

Description
Intensity of pain
Timepoint
Immediately, 5 and 10 minutes after leaving the venipuncture room
Method of measurement
Oucher pain scale

Intervention groups

1

Description
Intervention1: the physiological indicators of children will be measured in half an hour before entering into the venipuncture room and the children inhale 5 drops of lavender essence 2% which was poured onto 10×10 cm gauze attached to collar of children shirt in 20 minutes. Then, physiological indicators will be measured immediately after fixation of catheter and in minutes of 5 and 10 after exiting of venipuncture room. Intensity of pain will be measured in times of immediately, 5 and 10 after exiting of venipuncture room.

Category
Treatment - Drugs

2

Description
Intervention2: The physiological indicators of children will be measured in half an hour before entering into the venipuncture room and the children inhale 5 drops of distilled water (placebo) which was poured onto 10×10 cm gauze attached to collar of children shirt in 20 minutes. Then, physiological indicators will be measured immediately after fixation of catheter and in minutes of 5 and 10 after exiting of venipuncture room. Intensity of pain will be measured in times of immediately, 5 and 10 after exiting of venipuncture room.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Educational and Therapeutic Center

Full name of responsible person
Masoome Khaleghverdi

Street address
Department of Medical Surgical Nursing, Nursing and Midwifery School, Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamadan

City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person
Dr. Saeid Bashirian

Street address
vice chancellor for research Hamadan University of Medical Sciences, Hamadan University of Medical Sciences, Shahid Fahmide Street, Hamadan

City
Hamadan

Grant name

Grant code / Reference number

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

Title of funding source
vice chancellor for research, Hamadan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Department of Medical Surgical Nursing

Full name of responsible person
Dr. Ali Bikmoradi

Position
Medical Education Management

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty