

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of aromatherapy by essential oils of lavender and peppermint on the levels of pain and anxiety caused by the insertion of intravenous catheter

Protocol summary

Summary

Objective: To compare the effect of aromatherapy with essential oils of lavender and peppermint on the levels of pain and anxiety caused by the insertion of intravenous catheter. Design: randomized controlled clinical trial
Setting and conduct: sample size is 120 patients. Eligible patients will be selected by convenience sampling and will be randomly allocated to two interventions and one control groups. Inclusion and exclusion criteria: inclusion criteria include Consent to participate in the study, positive reaction to smell, and absence of allergies and chronic respiratory diseases. Exclusion criteria include Unwillingness to continue to cooperation, and failed first attempt at vascular access. Exclusion criteria include the patient's unwillingness to continuing the cooperation and the failure of the first IV catheterizing. Interventions: Initially the anxiety level will be measured by visual analogue scale. In groups one and two, essential oils of lavender and mint will be used respectively and in control group sterile water will be used. The essential oils will be spilled on the napkin and will be attached to the patient's clothing for 5 minutes, then intravenous catheter will be inserted. After fixing IV catheter, the levels of anxiety and pain will be measured by visual analogue scale and numerical scale respectively. The main outcome variables: pain and anxiety

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612124736N20**

Registration date: **2017-02-05, 1395/11/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-05, 1395/11/17

Registrant information

Name

Alireza Khatony

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 9394

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akhatony@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology,
Kermanshah University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-07-20, 1396/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of aromatherapy by essential oils of lavender and peppermint on the levels of pain and anxiety caused by the insertion of intravenous catheter

Public title

Effect of aromatherapy on pain and anxiety caused by the insertion of IV catheter

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion and exclusion criteria: inclusion criteria include Consent to participate in the study, positive reaction to smell, the absence of allergy and chronic respiratory diseases, and not using sedative and analgesic drugs from Six hours before the intervention Exclusion criteria include the patient's unwillingness to continuing the cooperation and the failure of the first IV catheterizing.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Comitee of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid Beheshty Street, Kermanshah, Iran

City

Kermanshah

Postal code

Approval date

2016-11-23, 1395/09/03

Ethics committee reference number

KUMS.RES.1395.570

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

2

Description of health condition studied

pain

ICD-10 code

M79.9

ICD-10 code description

Soft tissue disorder, unspecified

Primary outcomes

1

Description

Pain

Timepoint

after the IV insertion

Method of measurement

Numeric pain scale

2

Description

Anxiety

Timepoint

before and after the IV insertion

Method of measurement

Anxiety Visual Scale

Secondary outcomes

empty

Intervention groups

1

Description

In group two, the three drops of Peppermint essential oil will be used. Trade name of this essence is peppermint essential oil and its scientific name is Mentha piperita which is produced by Tehran Zardband Company. This essential oil will be used in pure form with a concentration of 100 percent. Major chemical compounds are Menthol and methyl acetate. Essential oils will be dropped by the dropper on a napkin and will be connected to the patient's clothing at the chest area and will be inhaled for 5 minutes

Category

Other

2

Description

In group one, the Three drops of lavender essential oil will be used. Trade name of this essence is lavender essential oil and its scientific name is Lavandula which is produced by Tehran Zardband Company. This essential

oil will be used in pure form with a concentration of 100 percent. Major chemical compounds are linalyl acetate and linalool. Essential oils will be dropped by the dropper on a napkin and will be connected to the patient's clothing at the chest area and will be inhaled for 5 minutes.

Category

Other

3

Description

In control group, the three drops of distilled water will be used which is produced by Tehran Samen Company. Distilled water will be dropped by the dropper on a napkin and will be connected to the patient's clothing at the chest area and will be inhaled for 5 minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Alireza Khatony

Street address

Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Street, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Kermanshah University of Medical Sciences

Full name of responsible person

Behrooz Hamzeh

Street address

Vice Chancellor for Research and Technology,
Kermanshah University of Medical Sciences, Shahid
Beheshty street, Kermanshah, Iran

City

Kermanshah

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 and Technology,
Kermanshah 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

Kermanshah School of Nursing and Midwifery

Full name of responsible person

alireza khatony

Position

PhD, Faculty Member

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Faculty member, PhD in Nursing Education

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Person responsible for updating data

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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