Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effectiveness of Lavandula aromatherapy for changing of patient's vital signs in ICU in Comparision to Midazolam

Protocol summary

Summary

A single blind clinical trial will be done in Intensive care unit . Inclusion criteria: age : between 20 – 80; Sex : Male and Female; GCS: higher than 8 and equal to 8; The Base of Vital sign is recorded when patient admitted to ICU then vital sign is measured and vital sign is recorded for one hour. Vital sign : Blood pressure , respiratory rate , pulse rate. Exclusion criteria: a history of chronic respiratory disease; history of lack smell sensation; history of respiratory allergy; GCS < 8. Patient is divided two group 32 person. Group 1: Aromatherapy; Group 2: Midazolam. The data collection will be done with the completation of questionnaire. The record of vital sign (heart rate , systolic BP , Diastolic Blood pressure , respiratory rate). Another data collection is demographic questionnaire consist of age , sex , height and weight . for doing Aromatherapy , 2 drop Essential oil 2% of Lavandula that is prepared by Danesh Bonyan E'jaz Kavir Shargh of iran(Shahrood) company, 2 drop of Essential oil of Lavandula is poured on patch and the patch is connected to inside Oxygen mask and the patient inhale for 20 minutes and in Midazolam group is injected 0.05 mg/kg intravenous . Vital sign is measured by monitor unit in 5 , 10 , 15 , 20 , 30 , 60 minutes after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081335666N1**
Registration date: **2017-09-06, 1396/06/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-06, 1396/06/15

Registrant information

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Maryam Harati
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Shahrood Branch

Expected recruitment start date

2017-07-27, 1396/05/05

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of Lavandula aromatherapy for changing of patient's vital signs in ICU in Comparision to Midazolam

Public title

Evaluation the effectiveness of Lavandula aromatherapy for changing of patient's vital signs in ICU in Comparision to Midazolam

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age : between 20 – 80; Sex : Male and Female; GCS: higher than 8 and equal to 8; The Base of

Vital sign is recorded when patient admitted to ICU then vital sign is measured and vital sign is recorded for one hour. Vital sign : Blood pressure , respiratory rate , pulse rate. Exclusion criteria: a history of chronic respiratory disease; history of lack smell sensation; history of respiratory allergy; GCS < 8.

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University Shahrood Branch

Street address
Shahrood , University Blvd , Islamic Azad University Shahrood Branch

City
Shahrood

Postal code

Approval date
2017-07-27, 1396/05/05

Ethics committee reference number
IR.IAU.SHAHROOD.REC.1396.10

Health conditions studied

1

Description of health condition studied
changing of patient's vital signs in ICU because of Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Blood Presure

Timepoint
5 min , 10 min , 15 min , 20 min , 30 min , 60 min

Method of measurement
mm Hg with Barometer

2

Description
Pulse rate

Timepoint
5 min , 10 min , 15 min , 20 min , 30 min , 60 min

Method of measurement
pulse rate in minutes

3

Description
respiratory rate

Timepoint
5 min , 10 min , 15 min , 20 min , 30 min , 60 min

Method of measurement
respiratory rate in minutes

Secondary outcomes

empty

Intervention groups

1

Description
Lavandula , 2 Drops 2% , inhalation for 20 minutes

Category
Treatment - Drugs

2

Description
Midazulam , IV , 0.05 mg/kg

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatamolanbia Hospital

Full name of responsible person

Street address
Khatamolanbia Hospital

City
Shahrood

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University Shahrood Branch
Full name of responsible person
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City
Shahrood
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University Shahrood Branch
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
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Web page address

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