

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 completion 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

Name

Maryam Harati

Name of organization / entity

Islamic Azad University Shahrood Branch

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 4530

Email address

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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 Pressure

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

Midazolam , IV , 0.05 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatamolania Hospital

Full name of responsible person

Street address

Khatamolania Hospital

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Shahrood Branch

Full name of responsible person

Maryam Harati

Street address

Shahrood , 7th Pishva st , Shahid Moghaddas Alley ,
plaque 122

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**Name of organization / entity**

Islamic Azad University Shahrood Branch

Full name of responsible person

Leila Khojasteh

Position

Anesthetist / Science Committee

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Full name of responsible person

Maryam Harati

Position

PhD student

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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