Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of lavender extract on pain of patients after middle ear surgery.

Protocol summary

Summary

Objective: The aim of this study is to evaluate of the effect of lavender extract on the severity of pain in patients with chronic otitist of the middle ear after surgery. Design: A randomized clinical trial. Setting: This study involved two groups of 50 patients undergoing chronic otitist surgery will be done. Each group consist of 25 patients people. Random allocation of samples will be done using block randomization.Intervention: Aromatherapy with lavender extract three consecutive days four times a day for patients after surgery will be done. The intervention is 4 drops of lavender essential oil for three minutes will inhale it. The control group consisted of routine nursing care is done by the staff.Before and after intervention to assess and compare pain intensity NSR scale is used. Inclusion criteria included: be conscious, lack of mental retardation, patient satisfaction in participating in the study. Exclusion criteria included: lack of patient cooperation during study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061825929N2**
Registration date: **2016-07-01, 1395/04/11**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2016-07-01, 1395/04/11

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

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Recruitment status

Not enough for processing

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

empty

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lavender extract on pain of patients after middle ear surgery.

Public title

The effect of lavender on pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: full consciousness; lack of mental retardation; patient satisfaction in participating in the study. Exclusion criteria: lack of patient cooperation during the study.

Age

From **20 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Hamedan University of Medical Sciences

Street address

Hamedan

City

Hamedan

Postal code

Approval date

2016-06-11, 1395/03/22

Ethics committee reference number

IR.UMSHA.REC.1395.122

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

H65.3

ICD-10 code description

Chronic mucoid otitis media

Primary outcomes

1

Description

pain

Timepoint

Before and after intervention

Method of measurement

NSRquestionnaire

Secondary outcomes

1

Description

Vital signs

Timepoint

before and after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

The control group consisted of routine nursing care is done by the staff

Category

Other

2

Description

In the intervention group aromatherapy with lavender extract four times a day for three minutes on three consecutive days after ear surgery will be done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Mehdi Molavi Vardanjani

Street address

Hamedan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hamedan University of Medical Sciences

Full name of responsible person

Mehdi Molavi Vardanjani

Street address

Hamedan

City

Hamedan

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 of Hamedan 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
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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