Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effect of inhalation aromatherapy on anxiety level, blood pressure and heart rate of the patients candidate for colonoscopy

Protocol summary

Summary

The aim of this study is to assess the effect of inhalation aromatherapy on the anxiety level,blood pressure and heart rate of patients who are candidate for colonoscopy. Design of this study is a randomized controlled clinical trial. A total of 100 patients with age of 18-65 years old ; without history of mental illnesses, asthma, olfactory dysfunction, allergy to the odor of the plants specially plants of peppremint and Lavender . Then the samples randomly were allocated in to Four groups: control group who inhaled the usual odor of the ward with Nebulizer mask; experimental group(1) who inhaled with nebulizer mask containing three drops of 100% Lavender essential oil and experimental group(2) who inhaled with nebulizer mask containing three drops of 100% peppremint essential oil and experimental group (3) who inhaled with nebulizer mask containing three drops of 100% Lavender essential oil and three drops of 100% peppremint essential oil. The interventions were performed on before of the colonoscopy . In order to data collection at first half an hour before of colonoscopy , the Spillberger questionnaire was filled out by the patients and physiologic criteria were assessed by the nurse. Again these stages were performed immediately before and after colonoscopy. In this study, primary outcome measure are anxiety and secondary outcome measures are blood pressure and pulse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015073123427N1**
Registration date: **2015-10-19, 1394/07/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-10-19, 1394/07/27

Registrant information

Name
Kazem Ayoubzadeh
Name of organization / entity
Birjand University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 56 3239 5000
Email address
kazem_ayobzadeh@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of inhalation aromatherapy on anxiety level, blood pressure and heart rate of the patients candidate for colonoscopy

Public title

Effect of inhalation aromatherapy on anxiety level, blood pressure and heart rate of the patients candidate for colonoscopy

Purpose

Other

Inclusion/Exclusion criteria
Inclusion criteria: age of 18-65 years old; without history of mental illnesses, epilepsy, asthma, thyroid, heart disease and olfactory dysfunction, allergy to the odor of plants specially plants of Peppermint and Lavender, the first experience of colonoscopy; willingness to participant in the study. Exclusion criteria: refuse to continue corporation in this study، use of Anti-anxiety drugs during the colonoscopy.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Sciences

Street address
Ghafari street, Birjand University of Medical Siences

City
Birjand

Postal code

Approval date
2015-07-27, 1394/05/05

Ethics committee reference number
Ir.bums.1394.31

Health conditions studied

1

Description of health condition studied
Colorectal Disease

ICD-10 code
K00-K93

ICD-10 code description
k55-k56-k57-k58-k59-k60-k61-k62-k63-k64-k65

Primary outcomes

1

Description
anxiety

Timepoint
half an hour before of colonoscopy and before and after of colonoscopy

Method of measurement
Spillberger questionnaire

Secondary outcomes

1

Description
blood pressure

Timepoint
half an hour before of colonoscopy and before and after of colonoscopy

Method of measurement
Cardiac monitoring device

2

Description
heart rate

Timepoint
half an hour before of colonoscopy and before and after of colonoscopy

Method of measurement
Cardiac monitoring device

Intervention groups

1

Description
In the control group: Patients inhaled the usual odor of the ward with Nebulizer mask

Category
Prevention

2

Description
In the experimental group (1): At once, by using a dropper three drops of 100 % Lavender essential oil were poured on the nebulizer. Then, the patient and asked to inhald with mask nebulizer for 15 min.

Category
Prevention

3

Description
In the experimental group (2): At once, by using a dropper three drops of 100 %peppremint essential oil were poured on the nebulizer. Then, the patient and

asked to inhald with mask nebulizer for 15 min.

Category

Prevention

4

Description

In the experimental group (2): At once, by using a dropper three drops of 100 %peppremint essential oil and three drops of 100 %lavender essential oil were poured on the nebulizer. Then, the patient and asked to inhald with mask nebulizer for 10 min.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

valiasr Hospital

Full name of responsible person

Street address

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Karbor Omolbanin

Street address

Ghaffari street

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Ayoubzadeh kazem

Position

Master of Sciences in nursing

Other areas of specialty/work

Street address

Street Ghaffari

City

Birjand

Postal code

Phone

+98 56 3239 5000

Fax

Email

kazem_ayobzadeh@bums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Ayoubzadeh kazem

Position

Master of Sciences in nursing

Other areas of specialty/work

Street address

Street Ghaffari

City

Birjand

Postal code

Phone

+98 56 3239 5000

Fax

Email

kazem_ayobzadeh@bums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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kazem_ayobzadeh@bums.ac.ir

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