Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Investigating the effect of inhalation and nebulization of peppermint plant essence on improving lung function in patients with asthma referred to a medical clinic

Protocol summary

Study aim

Determining the effect of inhalation and nebulization of peppermint plant essence on improving lung function in patients with asthma referred to a medical clinic

Design

The trial includes a control and intervention group with a double-blind relationship and each group has 24 people randomly, which is a total of 48 people. The division is based on block randomization.

Settings and conduct

People did not use anti-asthma drugs 6 hours before spirometry, and then these patients were given 1.4 ml of peppermint essence (mint solution and ethanol) or placebo (ethanol and distilled water) (randomly in two treatment and control groups). It is given as nebulization and under controlled conditions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: men and women with grade 2 and 3 asthma diagnosed by a specialist doctor. Age range from 18 to 65 years. No allergic symptoms and acute respiratory disease. Exclusion criteria: people with reflux, pregnant women, hepatobiliary patients, patients who have been infected with or recovered from COVID-19 but still suffer from its respiratory symptoms, as well as people who have uncontrolled blood pressure and are allergic to mint.

Intervention groups

Among the clients of the treatment center, 48 people with asthma (grade 2 and 3) voluntarily participated in this research. In this clinical trial, 48 patients with asthma are first visited by an asthma and allergy specialist. After confirming the asthma of these people and according to the entry conditions, patients are given forms to check how and when to take the latest drugs (bronchodilators and anti-inflammatories) and monitor the level of the disease (attached).

Main outcome variables

Measuring the amount of changes in fev1 to fvc ratio after nebulization of peppermint essential oil The ratio of FEV1 to FVC Measuring the amount of ductal inflammation in referring patients using feNO

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231030059905N1**
Registration date: **2024-01-21, 1402/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-21, 1402/11/01**
Update count: **0**

Registration date

2024-01-21, 1402/11/01

Registrant information

Name

Ali Haghbin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3222 5298

Email address

dr.haghbin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of inhalation and nebulization of peppermint plant essence on improving lung function in patients with asthma referred to a medical clinic

Public title

Investigating the effect of peppermint essential oil inhalation on improving lung function in patients with asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with level 2 or 3 asthma who have visited the clinic and have no acute respiratory problems

Exclusion criteria:

Measuring sensitivity to mint (one of the exit criteria): by taking a history of the symptoms of an allergic reaction to mint (itching, hives, shortness of breath). Lack of personal satisfaction Lack of bronchodilator-responsive asthma High grades of asthma with clinical symptoms such as chronic and severe shortness of breath

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The division is done based on block randomization. Eligible patients will be randomly assigned using permuted blocked randomization (1:1) with a block size of 4 into two groups: an intervention group receiving inhalation (nebulizer) of peppermint plant essential oil and a placebo group. The order of blocks will also be randomized. According to the permuted blocked randomization scheme of the study, the whole randomization list will be created before a single patient is enrolled. Then, the prepared list will be numbered from the beginning of the list. The assignment of numbers to the study groups will be kept confidential and not shared with the research team. Therefore, with this numbering, the research team involved in the intervention process will be blinded to the allocated treatment. These numbers will be also included in the pockets of inhalation (nebulizer) of peppermint plant essential oil and its placebo. Upon randomization into the trial, patients will receive the next sequential assignment based on the randomization list.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researchers will try to blind the medical team involved in the entire interventional process for the allocated treatment. However, as the essential oil has its special odor, the blinding will not be perfect. This will be mentioned in the limitations of the relevant paper. Eligible patients will be randomly assigned using permuted blocked randomization (1:1) with a block size of 4 into two groups: an intervention group receiving inhalation (nebulizer) of peppermint plant essential oil and a placebo group. The order of blocks will also be randomized. According to the permuted blocked randomization scheme of the study, the whole randomization list will be created before a single patient is enrolled. Then, the prepared list will be numbered from the beginning of the list. The assignment of numbers to the study groups will be kept confidential and not shared with the research team. Therefore, with this numbering, the research team involved in the intervention process will be blinded to the allocated treatment. These numbers will be also included in the pockets of inhalation (nebulizer) of peppermint plant essential oil and its placebo. Upon randomization into the trial, patients will receive the next sequential assignment based on the randomization list.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of North Khorasan University of Medical Sciences

Street address

Bojnourd , chamran str , chamran36

City

Bojnourd

Province

North Khorasan

Postal code

9413884648

Approval date

2023-11-19, 1402/08/28

Ethics committee reference number

IR.NKUMS.REC.1402.123

Health conditions studied

1

Description of health condition studied
Asthma disease, patients with grade 2 and 3 asthma
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
The amount of air that leaves the lungs during the first second of forced exhalation(FEV1)
Timepoint
Measurement of variables in both control and control groups, before the start of the study, half an hour after inhaling the essential oil.
Method of measurement
Spirometry, feNO test, demographic information is completed by questionnaire

2

Description
FVC
Timepoint
Measurement of variables in both control and control groups, before the start of the study, half an hour after inhaling the essential oil.
Method of measurement
Spirometry

3

Description
The ratio of FEV1 to FVC
Timepoint
Measurement of variables in both control and control groups, before the start of the study, half an hour after inhaling the essential oil.
Method of measurement
Spirometry

4

Description
The amount of peppermint essential oil
Timepoint
Measurement of variables in both control and control groups, before the start of the study, half an hour after inhaling the essential oil.
Method of measurement
ml

5

Description
Demographic information
Timepoint
Before starting the study
Method of measurement
Examining patients' files and asking the patient or his companion

Secondary outcomes

1

Description
Improve lung function
Timepoint
Immediately 15 to 30 minutes after inhalation
Method of measurement
FVC , FVC, The ratio of FEV1 to FVC

Intervention groups

1

Description
Intervention group: women and men with grade 2 and 3 asthma diagnosed by a specialist doctor. Age range from 18 to 65 years. Without allergic symptoms and acute respiratory disease. People did not use anti-asthma drugs 6 hours before spirometry, and these patients were given 1.4 ml of peppermint essence (mint solution and ethanol). After 15 to 30 minutes of peppermint essential oil nebulization, FEV1 to FVC level is again measured and recorded.
Category
Treatment - Drugs

2

Description
Control group: women and men with grade 2 and 3 asthma diagnosed by a specialist doctor. Age range from 18 to 65 years. No allergic symptoms and acute respiratory disease. This group will receive placebo (ethanol and distilled water) and according to the block randomization system, other cases that were done in the intervention group will also be done on this group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
imam reza hospital
Full name of responsible person
Ali Haghbin
Street address
Bojnourd,Dolat Blvd, Central Building of North Khorasan University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Dr Bahram Bibak
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Dr Ali Haghbin
Position
Specialist in immunology and clinical allergy and university faculty
Latest degree
Subspecialist
Other areas of specialty/work
Specialist in immunology and clinical allergy
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Person responsible for scientific inquiries

Contact
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Latest degree
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Person responsible for updating data

Contact
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Full name of responsible person
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Bachelor
Other areas of specialty/work
Nursery
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ramezani80amirhosein@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic information form, informed consent, evaluations before and after the study and clinical trial, trial results, analysis table are shared at the end of the study.
When the data will become available and for how long
Access 6 months after printing the results
To whom data/document is available
Qualified researchers
Under which criteria data/document could be used
Just to monitor and also help in scientific promotion . After getting approval from the first author and the project consultant
From where data/document is obtainable
First author and project consultant
What processes are involved for a request to access data/document
Getting written approval from the first author and the person in charge and consultant of the project
Comments