

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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

##### City

Bojnord

##### Province

North Khorasan  
**Postal code**  
74877-94149  
**Phone**  
+98 58 3151 0000  
**Fax**  
**Email**  
INFO@NKUMS.AC.IR

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Bojnourd University of Medical Sciences  
**Full name of responsible person**  
Dr Bahram Bibak  
**Street address**  
Dolat Blvd., Central Building of North Khorasan  
University of Medical Sciences, Bojnourd  
**City**  
Bojnourd  
**Province**  
North Khorasan  
**Postal code**  
74877-94149  
**Phone**  
+98 58 3151 0000  
**Email**  
INFO@NKUMS.AC.IR

#### 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

#### Street address

Dolat Blvd., Central Building of North Khorasan  
University of Medical Sciences, Bojnourd

#### City

Bojnourd

#### Province

North Khorasan

#### Postal code

74877-94149

#### Phone

+98 58 3151 0000

#### Email

INFO@NKUMS.AC.IR

## Person responsible for scientific 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  
**Street address**  
Dolat Blvd., Central Building of North Khorasan  
University of Medical Sciences, Bojnourd  
**City**  
Bojnourd  
**Province**  
North Khorasan  
**Postal code**  
74877-94149  
**Phone**  
+98 58 3151 0000  
**Email**  
INFO@NKUMS.AC.IR

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Bojnourd University of Medical Sciences  
**Full name of responsible person**  
Amirhosein Ramezani  
**Position**  
Nursing Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No. 724, 36 Chamran Street, Kargar Square, Bojnourd  
**City**  
Bojnourd

**Province**

North Khorasan

**Postal code**

9413884648

**Phone**

+98 58 3222 8129

**Email**

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**