# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of nebulizing Peppermint extract and Rose extract on percentage of blood oxygen saturation in patients with COVID-19

### Protocol summary

**Study aim**
The effect of nebulizing Peppermint extract and Rose extract on percentage of blood oxygen saturation in patients with COVID-19

**Design**
Patient candidate for with evidences of COVID-19 in chest CT Scan and candidate for hospitalizing randomly and with using table of random number divided in 3 groups and each group contain 20 individuals. Groups; Peppermint group, Rose oil group and control's group. Sample size 60 was determined that divided in 3 groups. Clinical trial, single blind, with control group.

**Settings and conduct**
Patients with evidences of COVID-19 in chest CT Scan and candidate for hospitalizing in Shohadaye Tajrish hospital divided in groups and participants have no information about groups and receiving medication or placebo.

**Participants/Inclusion and exclusion criteria**
Patients with evidence of COVID-19 in Chest CT Scan Without history of Asthma or Chronic Obstruction Pulmonary Disease Without history of Allergy

**Intervention groups**
Three groups; The first group receive nebulizing of peppermint extract and the second group receive nebulizing of Rose extract and the third group (control) receive nebulizing of distilled water as placebo.

**Main outcome variables**
Percentage of blood oxygen saturation in patients with COVID-19

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190131042569N5**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **registered_while_recruiting**
Last update: **2020-08-23, 1399/06/02**
Update count: **0**

**Registration date**
2020-08-23, 1399/06/02

**Registrant information**

**Name**
Nima saeedi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 2641 8939

**Email address**
nimasaeedi@sbmu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-06-29, 1399/04/09

**Expected recruitment end date**
2020-09-21, 1399/06/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of nebulizing Peppermint extract and Rose extract on percentage of blood oxygen saturation in patients with COVID-19

**Public title**
The effect of nebulizing Peppermint extract and Rose extract on percentage of blood oxygen saturation in patients with COVID-19

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with evidence of COVID-19 in Chest CT Scan Age between 30 and 60 years

**Exclusion criteria:**

History of Asthma or Chronic Obstruction Pulmonary Disease History of Allergy

**Age**

From **30 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Each patient who qualify for inclusion after completing the consent form is assigned by the person in charge of this process using a random number table from 1 to 60 ( 1- 20 Peppermint group, 21-40 Rose oil group and 41-60 control group) where the person is placed on one of the numbers and assigned to one of the 2 specified groups. (Simple randomization by individual using random number table).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The person responsible for follow-up and recordings data has no information about the patient's group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti University of Medical Science, Arabi Ave., Daneshjoo Blvd., Velenjak, Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2020-06-28, 1399/04/08

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.353

## Health conditions studied

### 1

**Description of health condition studied**

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified, confirmed by laboratory testing

## Primary outcomes

### 1

**Description**

Increasing of percentage of blood oxygen saturation

**Timepoint**

Measurement of blood oxygen saturation percentage at the beginning of the study, the first day, the second day and the third day of treatment

**Method of measurement**

Pulse oximetry

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group 1 : From the beginning of treatment, patients receive Nebulizing of Peppermint extract from Barij Essence brand (15 drops in 30 cc of distilled water) daily and each time for 2 hours for 3 days.

**Category**

Rehabilitation

### 2

**Description**

Intervention group 2 : From the beginning of treatment, patients receive Nebulizing of Rose extract from Barij Essence brand (15 drops in 30 cc of distilled water) daily and each time for 2 hours for 3 days.

**Category**

Rehabilitation

### 3

**Description**

Control group: From the beginning of treatment, patients receive Nebulizing of distilled water(30 cc) daily and each time for 2 hours for 3 days.

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shohadaye Tajrish Hospital
**Full name of responsible person**
Nima Saeedi
**Street address**
Shohadaye Tajrish Hospital, Tajrish Square, Tehran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Research Department of Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Seyed Ali Ziayi
**Street address**
Third floor, School of Medicine, near the Taleghani Hospital, Evin, Shahid Chamran Highway
**City**
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**Email**
mpd@sbmu.ac.ir
**Web page address**
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Research Department of Shahid Beheshti 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**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Nima Saeedi
**Position**
Anesthesia assistance
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
No. 11, First East Ave., Bistochahar metri Ave., Tehran.
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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## 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**
Participant data (age, percentage of blood oxygen saturation and type of patient's group) are to be shared.

**When the data will become available and for how long**
1 year after publication

**To whom data/document is available**
Researchers working in academic institutions

**Under which criteria data/document could be used**
Using data and analysis for use in academic research

**From where data/document is obtainable**
Send Email Dr.Nima Saeedi Email Address: nimasaeedi7@yahoo.com

**What processes are involved for a request to access data/document**
Send request via Email and after 1 week will be replied.

**Comments**