

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 May 2021

### 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@sbm.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  
**City**  
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**Province**  
Tehran  
**Postal code**  
1989934148  
**Phone**  
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pr\_shohada@sbmu.ac.ir

## 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**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717434  
**Phone**  
+98 21 2243 9951  
**Fax**  
**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., Bistochar metri Ave., Tehran.  
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1997778416  
**Phone**  
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nimasaeedi7@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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1997778416

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**Fax****Email**

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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**