

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2022

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
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1989934148
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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
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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
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Anesthesiology
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Person responsible for updating data**Contact****Name of organization / entity**

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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