Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The effect of inhalation of orange peel and peppermint extract on reducing the severity of COVID-19 symptoms in patients referred to clinic with a positive result of lung CT scan

Protocol summary

Study aim
Determining the effect of inhaling orange peel and peppermint essence on reducing the severity of COVID-19 symptoms in outpatients referred to clinic with a positive result of lung CT scan

Design
Clinical trial included of control group, without blinding, randomized and phase 3 on 60 patients. Randomize Allocation Software was used for randomization.

Settings and conduct
After completing a questionnaire and interview, checklist , CT scan and physical examination the patients with COVID-19 symptoms , were given the medication in the control group and placebo in the case group with the training how to perform the protocol .These steps happened again in 72 hours and a week later.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Pulmonary involvement on CT scan suspected to covid-19 disease, Having suspected clinical signs of covid-19 disease, Informed consent to participate in the study, Availability to incense the solution, Availability to visit after 72 hours, No need for hospitalization at the time of referrals Non Inclusion: Hospitalization, Non-pulmonary symptoms

Intervention groups
In the intervention group, a combination of orange peel and peppermint essence is given in a dropper bottle. People should pour 20 drops of this solution into a glass of water and boil it in a metal container on a pot and inhale its steam. In the control group, patients will receive their routine medications and use only incense in a glass of boiled water as a placebo.

Main outcome variables
Fever, Dyspnea, Tachypnea, Cough, Diarrhea, Myalgia, Headache, Rash, Tachycardia, Chest pain, SPO2, CT Scan result

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110302005952N2**
Registration date: **2020-12-17, 1399/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-17, 1399/09/27**
Update count: **0**

Registration date
2020-12-17, 1399/09/27

Registrant information

Name
Masoud Hafizi esfahani

Name of organization / entity
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-25, 1399/09/05

Expected recruitment end date
2020-12-25, 1399/10/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of inhalation of orange peel and peppermint extract on reducing the severity of COVID-19 symptoms in patients referred to clinic with a positive result of lung CT scan

Public title
The effect of orange peel and peppermint extract in coronavirus treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pulmonary involvement on CT scan suspected to COVID-19 disease Having suspected clinical signs of COVID-19 disease Informed consent for participating in the study Possibility to visit after 72 hours No need for hospitalization at the time of referral Possibility of inhaling the solution

Exclusion criteria:
Hospitalized patient Non-respiratory symptoms suspected to COVID-19 disease

Age
From **10 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Bldg No. 2, Kahani Blvd, University Headquarter

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Approval date
2020-07-12, 1399/04/22

Ethics committee reference number
IR.SKUMS.REC.1399.107

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.2

ICD-10 code description
U07.2 COVID-19, virus not identified

Primary outcomes

1

Description
Fever

Timepoint
72 hours and one week after the first visit

Method of measurement
Thermometer

2

Description
Dyspnea

Timepoint
72 hours and one week after the first visit

Method of measurement
Non - Mild - Moderate - Severe

3

Description
Tachypnea

Timepoint
72 hours and one week after the first visit

Method of measurement
Inspiration/Minute

4

Description
Cough

Timepoint
72 hours and one week after the first visit

Method of measurement
Non - Mild - Moderate - Severe

5

Description
Diarrhea

Timepoint
72 hours and one week after the first visit
Method of measurement
Non - Mild - Moderate - Severe

6

Description
Myalgia
Timepoint
72 hours and one week after the first visit
Method of measurement
Visual Analogue Scale

7

Description
Headache
Timepoint
72 hours and one week after the first visit
Method of measurement
Visual Analogue Scale

8

Description
Rash
Timepoint
72 hours and one week after the first visit
Method of measurement
Visual Analogue Scale

9

Description
Tachycardia
Timepoint
72 hours and one week after the first visit
Method of measurement
Visual Analogue Scale

10

Description
Chest Pain
Timepoint
72 hours and one week after the first visit
Method of measurement
Visual Analogue Scale

11

Description
SPO2
Timepoint
72 hours and one week after the first visit
Method of measurement
Visual Analogue Scale

12

Description
CT Scan Result
Timepoint
One week after the first visit
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Increasing the SPO2 with taking medication
Timepoint
72 hours and one week after the first visit
Method of measurement
Pulse Oximeter

2

Description
Shortening the Illness duration
Timepoint
72 hours and one week after the first visit
Method of measurement
Time Interval

3

Description
Reducing Pulmonary Inflammation
Timepoint
72 hours and one week after the first visit
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: The extract prepared from 14 cc of orange peel essential oil prepared from Ramsar Citrus Cooperative and 2 cc of peppermint essential oil in a 20 cc dropper bottle along with the instruction sheet is given to the patient. The patient will be trained to pour 20 drops of this solution in a glass of water and boil it in a metal container on a pot and inhale its steam (incense) and to do this three times a day until the medicine is finished.
Category
Treatment - Drugs

2

Description
Control group: Pour a glass of water in a metal container and boil it on a pot and breathe its steam (incense). Do this three times a day until the medicine is finished.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic No.1, Social Security
Full name of responsible person
Mohammadali Ghiasi
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2

Recruitment center
Name of recruitment center
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3

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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https://research.skums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
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Specialized Physician
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available