

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

hafizi@skums.ac.ir

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

Street address

Moulavi Ave

City

Sharekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8817686135

Phone

+98 38 3225 2341

Fax**Email**

vahid_ghiaci@yahoo.com

2

Recruitment center

Name of recruitment center

Hajar Respiratory Clinic

Full name of responsible person

Masoud Hafizi Isfahani

Street address

Parastar Ave

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 38 3222 5505

Fax

+98 38 3224 3715

Email

hafizi@skums.ac.ir

Web page address

3

Recruitment center

Name of recruitment center

Ali Asghar Clinic

Full name of responsible person

Reza Imani

Street address

Alley No. 31, 17 Shahrivar Ave

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814855116

Phone

+98 38 3335 0993

Email

imanir46@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

Bldg No.2, Kashani Blvd, University Headquarter

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3334 2414

Email

vcrt@skums.ac.ir

Web page address

<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**Name of organization / entity**

Social Security

Full name of responsible person

Mohammadali Ghiasi

Position

Specialized Physician

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Molavi Ave, Clinic No.1, Social Security

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8817686135

Phone

+98 38 3225 2341

Email

vahid_ghiacy@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Social Security

Full name of responsible person

محمد علی غیائی

Position

Specialized Physician

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Molavi Ave, Clinic No.1, Social Security

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8817686135

Phone

+98 38 3225 2341

Email

vahid_ghiacy@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Masoud hafizi isfahani

Position

Specialized Physician

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Parastar Ave, Hajar Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 38 3222 5505

Fax

+98 38 3224 3715

Email

hafizi@skums.ac.ir

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