

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Inhalation of Thyme Oil with Standard Nationwide Medication on Respiratory Markers and Laboratory Findings in Patients with COVID-19

Protocol summary

Study aim

Determination of The Effect of Inhalation of Thyme Oil with Standard Nationwide Medication on Respiratory Markers and Laboratory Findings in Patients with COVID-19

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized block, phase 2-3 on 48 patients. Random chains and concealment codes were produced by the website "www.sealedenvelope.com".

Settings and conduct

This randomized double-blind study was performed at Khatam al-Anbia hospital in Shoushtar. The standard nationwide medication + Intervention Group receives pure thyme essential oil through a nebulizer (every 8 hours for 30 minutes) for 5 days. Also, the control group receives a standard nationwide medication + 10 cc of distilled water as a placebo through a nebulizer (every 8 hours for 30 minutes) for 5 days. All research teams except the lead researcher and the treating physician will be blind, and the information will be given to the analyzer by the treating physician with a special code extracted from the table of random numbers.

Participants/Inclusion and exclusion criteria

Age over 18 years; Mild to moderate disease; Positive polymerase chain reaction (PCR) test; Lung involvement based on CT scan; Hospitalization

Intervention groups

The intervention group in addition to receiving standard nationwide medication receives pure thyme oil every 8 hours for 30 minutes through a nebulizer for 5 days. Also, the Control group in addition to receiving standard nationwide medication receives 10 cc of distilled water (placebo) every 8 hours for 30 minutes through a nebulizer for 5 days. The standard nationwide medication is as follows: 2 tablets of Hydroxychloroquine sulfate 200 mg as a single dose and 2 tablets of Kaletra

(Lopinavir/Ritonavir) 200/200 mg every 12 hours

Main outcome variables

Percentage of oxygen saturation; Respiratory rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200426047212N1**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **prospective**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Ali Hatami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 7153

Email address

hatami_a@shoushtarums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Inhalation of Thyme Oil with Standard Nationwide Medication on Respiratory Markers and Laboratory Findings in Patients with COVID-19

Public title

Effect of of Inhalation of Thyme Oil in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Mild to moderate disease Positive polymerase chain reaction (PCR) test Lung involvement based on CT scan Hospitalization

Exclusion criteria:

Patient death Sensitivity to inhalation of the drug Intolerance of nebulizer Physician's diagnosis of not participating in the study Pregnancy and lactation Use of angiotensin-converting enzyme inhibitor Severe renal, hepatic, respiratory and cardiovascular failure Taking cytotoxic or corticosteroid drugs Transfer to another hospital

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of samples to each of the intervention and control groups was performed by block random method using 4 blocks. Random chains and concealment codes were generated by the website "www.sealedenvelope.com". To hide the random chain, the method of envelopes in non-transparent packages is also used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Thyme oil and placebo oil is imported in uniform bottles of the same color and is given to patients and clinical caregivers in envelopes A and B. Thyme oil does not have a special smell and using the allowed color, the placebo is the same color as the medicine. All research teams except the lead researcher and the treating physician will be blind, and the information will be given to the analyzer by the treating physician with a special code extracted from the table of random numbers.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shoushtar Faculty of Medical Sciences

Street address

Shahid Rajaei Ave., Al-Hadi Hospital, Education, Research, Cultural and Student Department of Shushtar Faculty of Medical Sciences

City

Shoushtar

Province

Khouzestan

Postal code

6451684534

Approval date

2020-04-22, 1399/02/03

Ethics committee reference number

IR.SHOUSHTAR.REC.1399.005

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Percentage of oxygen saturation

Timepoint

Before the start of the intervention, 5 consecutive days during the intervention and one day after the intervention

Method of measurement

Pulse oximeter

2**Description**

Respiratory rate

Timepoint

Before the start of the intervention, 5 consecutive days during the intervention and one day after the intervention

Method of measurement

Count the respiratory rate per minute

Secondary outcomes

1

Description

C-Reactive Protein

Timepoint

Before the intervention and one day in between during the intervention until discharge

Method of measurement

Venous blood test

2

Description

White blood cell

Timepoint

Before the intervention and one day in between during the intervention until discharge

Method of measurement

Venous blood test

3

Description

Neutrophil

Timepoint

Before the intervention and one day in between during the intervention until discharge

Method of measurement

Venous blood test

4

Description

Lymphocytes

Timepoint

Before the intervention and one day in between during the intervention until discharge

Method of measurement

Venous blood test

5

Description

Red blood count

Timepoint

Before the intervention and one day in between during the intervention until discharge

Method of measurement

Venous blood test

6

Description

Erythrocyte sedimentation rate

Timepoint

Before the intervention and one day in between during the intervention until discharge

Method of measurement

Venous blood test

Intervention groups

1

Description

Intervention group: The intervention group in addition to receiving a standard nationwide medication [2 tablets of Hydroxychloroquine sulfate 200 mg as a single dose and 2 tablets of Kaletra(Lopinavir/Ritonavir) 200/200 mg every 12 hours], receives pure thyme oil every 8 hours (8 am, 4 pm, 12 pm) for 30 minutes through a nebulizer for 5 days. So that 4 drops of pure thyme oil with 10 cc of distilled water were prepared for each nebulization.

Category

Treatment - Drugs

2

Description

Control group: The control group in addition to receiving a standard nationwide medication [2 tablets of Hydroxychloroquine sulfate 200 mg as a single dose and 2 tablets of Kaletra(Lopinavir/Ritonavir) 200/200 mg every 12 hours], receives 10 cc of distilled water (placebo) every 8 hours (8 am, 4 pm, 12 pm) for 30 minutes through a nebulizer for 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al-Anbiya hospital

Full name of responsible person

Hassan Hassanzadeh Namin

Street address

Ammar Ave., Jazayeri Blvd., First of Farhang City

City

Shoushtar

Province

Khouzestan

Postal code

6451684534

Phone

+98 61 3623 3890

Email

hatami_a@shoushtarums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shooshtar University of Medical Sciences

Full name of responsible person

Barat Barati

Street address

Shahid Rajaei Ave., Al-Hadi Hospital, Education,
Research, Cultural and Student Department of
Shushtar Faculty of Medical Sciences

City

Shoushtar

Province

Khouzestan

Postal code

6451684534

Phone

+98 61 3622 8926

Email

barati-b@shoushtarums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shooshtar 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

Shooshtar University of Medical Sciences

Full name of responsible person

Ali Hatami

Position

Staff

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Rajaei Ave., Al-Hadi Hospital, Education,
Research, Cultural and Student Department of
Shushtar Faculty of Medical Sciences

City

Shoushtar

Province

Khouzestan

Postal code

6451684534

Phone

+98 61 3622 8926

Email

hatami_a@shoushtarums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shooshtar University of Medical Sciences

Full name of responsible person

Mohammad Nikzadian

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Rajaei Ave., Al-Hadi Hospital, Education,
Research, Cultural and Student Department of
Shushtar Faculty of Medical Sciences

City

Shoushtar

Province

Khouzestan

Postal code

6451684534

Phone

098 61 36228926

Email

nikzadian-m@shoushtarums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shooshtar University of Medical Sciences

Full name of responsible person

Ali Hatami

Position

Staff

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Rajaei Ave., Al-Hadi Hospital, Education,
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Shushtar Faculty of Medical Sciences

City

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Province

Khouzestan

Postal code

6451684534

Phone

+98 61 3622 8926

Email

hatami_a@shoushtarums.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