Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shooshtar University of Medical Sciences

Full name of responsible person
Barat Barati

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

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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

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Mohammad Nikzadian

Position
Instructor

Latest degree
Master

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Nursery

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Person responsible for updating data

Contact

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Position
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Other areas of specialty/work
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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