

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of therapeutic effects of oral eucalyptus tablets on the treatment process of patients with Covid 19 infection.

Protocol summary

Study aim

The effect of eucalyptus pills on the recovery process of patients with covid19

Design

This study is a clinical trial with a control group, with parallel groups, three-way blind, randomized, phase 3 on 50 patients and for randomization the rand function of Excel software is used. Patients are randomly divided into intervention and control groups.

Settings and conduct

This study is performed on 50 patients in Firoozabadi Hospital. Patients should receive the standard treatment regimen according to the national guidelines of the fifth version of Coronavirus treated with Eucalyptus soft oral capsule from Barij Essence Pharmaceutical Company as one oral capsule every 8 hours for 7 days. This study is three-way blind, so that the subject and the clinician conducting the research who monitors the patients and the statistical analyzer are unaware of the status of the two groups assigned to the study. Labels on medicine packages will be removed. Only one observer will be aware of the allocation of groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 40 and 60 years with Covid 2019 infection admitted to Firoozabadi Hospital / Inclusion criteria: Patients under 40 years and over 60 years / Patients with liver disease / Patients with known heart disease / Patients with immunodeficiency / Intubated patients with Inflammatory diseases of the gastrointestinal tract

Intervention groups

Patients with inclusion criteria after randomization are divided into two groups: intervention and control. One pill is taken every 8 hours for 7 days. The control group is undergoing medical intervention and receives a standard treatment regimen according to the national protocol.

Main outcome variables

Shortness of breath based on NYHCA scale/Blood oxygen level (SPO2%) Inflammatory indicators of CRP/Blood

lymphocyte count/White blood cell count/Body temperature/Respiration rate/Cough

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200913048701N1**

Registration date: **2020-09-22, 1399/07/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-22, 1399/07/01**

Update count: **0**

Registration date

2020-09-22, 1399/07/01

Registrant information

Name

Hossein Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3625 6451

Email address

shirazi.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-10-01, 1399/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of oral eucalyptus tablets on the treatment process of patients with Covid 19 infection.

Public title

Evaluation of effects of eucalyptus tablets on the process of covid 19 disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between 40 and 60 years of age with new coronavirus infection 2019 who have been admitted to Firoozabadi Hospital.

Exclusion criteria:

Age over 60 years Age under 40 years No hospitalization No infection with coronavirus 2019

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after obtaining informed consent from eligible individuals, individuals will be randomly divided into two groups using the number table method. In this way, patients who are candidates for inclusion in the study, after reviewing the inclusion and exclusion criteria and obtaining informed consent, a number will be given to people using the software, and based on this random number, people will be given one of the two The study group will belong.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is three-way blind, so that the subject and the clinician conducting the research who monitors the patients and the statistical analyzer are unaware of the status of the two groups assigned to the study. Labels on medicine packages will be removed. The subject is not aware of the status of assignment to groups. The researcher who makes clinical and diagnostic measurements will not be aware of the status of individuals, nor will the statistical consultant be unaware of the allocation of individuals to study groups. Only one observer will be aware of the allocation of groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-09-13, 1399/06/23

Ethics committee reference number

IR.IUMS.REC.1399.534

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

COVID-19 disease

ICD-10 code

U07.1

ICD-10 code description

COVID-19

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

Blood oxygen level (SPO2%)

Timepoint

Before the intervention, and 3, 5 and 7 days after the intervention

Method of measurement

Pulse oximeter device

2**Description**

Inflammatory index CRP

Timepoint

Before the intervention, and 3, 5 and 7 days after the intervention

Method of measurement

blood test

3

Description

Cough

Timepoint

Before the intervention, and 3, 5 and 7 days after the intervention

Method of measurement

Qualitative (mild-moderate-severe)

4

Description

Blood lymphocyte count

Timepoint

Before the intervention, and 3, 5 and 7 days after the intervention

Method of measurement

blood test

5

Description

White blood cell count

Timepoint

Before the intervention, and 3, 5 and 7 days after the intervention

Method of measurement

blood test

Secondary outcomes

1

Description

The rate of disease progression

Timepoint

Before the intervention, and 3, 5 and 7 days after the intervention

Method of measurement

Researcher checklist

2

Description

Duration of hospitalization

Timepoint

Before the intervention and 7 days after the intervention

Method of measurement

Researcher checklist

Intervention groups

1

Description

Intervention group: Patients undergoing intervention with Eucalyptus soft oral capsule from Barij Essential Oil Company containing Eucalyptus essential oil (Eucalyptus globulus) Active ingredients 8 (Cineol (Eucalyptol), Alpha-

Pinene, Lemonene) in accordance with the approved drug catalog of the Food and Drug Administration 8 hours for 5 days

Category

Treatment - Drugs

2

Description

Control group: Patients are not intervened.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozabadi Hospital

Full name of responsible person

Dr Fateme Tajikrostami

Street address

Firoozabadi Hospital, Fadaiyan-e-Islam St., Tehran ; Iran

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1849794113

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Hossein Shirazi

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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