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
City
Tehran
Province
Tehran
Postal code
1849794113
Phone
+98 21 5590 0243
Email
hospfa@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Abbas Motavlian
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
ivco@iums.ac.ir
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

Street address
No. 49, Taleghani Ave., Miri Blvd., Varamin Town

City
Varamin

Province
Tehran

Postal code
3371673634

Phone
+98 21 3625 6451

Fax

Email
shirazi.h@iums.ac.ir

Person responsible for scientific 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

Street address
No. 49, Taleghani Ave., Miri Blvd., Varamin Town

City
Varamin

Province
Tehran

Postal code
3371673634

Phone
+98 21 3625 6451

Fax

Email
shirazi.h@iums.ac.ir

Person responsible for updating data

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

Street address
No. 49, Taleghani Ave., Miri Blvd., Varamin Town

City
Varamin

Province
Tehran

Postal code
3371673634

Phone
+98 21 3625 6451

Fax

Email
shirazi.h@iums.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