Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of alcoholic extract of the olive leaf on clinical and Laboratory outcomes of patients with Covid-19

Protocol summary

Study aim

Determining the effect of olive leaf extract on clinical and laboratory outcomes of patients with Covid-19

Design

A randomized, three-sided, randomized controlled clinical trial on 129 patients was used using the randomized block method of Excel software.

Settings and conduct

The study population is all patients with Covid-19 hospitalized in the general wards of Shahid Labbafinejad Hospital in Tehran. The groups will evaluate the participants in terms of age, sex, and lung involvement with a standardized block block. The researcher will evaluate the study participants using a clinical outcome questionnaire and a laboratory findings questionnaire. Then he puts the medicine packages that he, the patient and the statistics consultant are unaware of in the participants' medicine box and asks the ward nurses to provide the medicine to the participants twice a day for 5 days.

Participants/Inclusion and exclusion criteria

Admission: All patients with Covid - 19 approved by the doctor - Age 18-70 years - Level of consciousness 15 Withdrawal: taking supplements containing oleopurine - any underlying disease - pregnancy and lactation - hypoglycemia - hypotension - unwillingness to cooperate - allergies - not taking the right medication

Intervention groups

Olive leaf extract group at a dose of 250 mg twice a day for five days Olive leaf extract group at a dose of 500 mg twice a day for five days control group Use of wheat placebo in capsules of the same shape with intervention groups twice a day for five days

Main outcome variables

Temperature, blood pressure, heart rate, percentage of arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049520N1**
Registration date: **2021-02-22, 1399/12/04**
Registration timing: **prospective**

Last update: **2021-02-22, 1399/12/04**
Update count: **0**

Registration date

2021-02-22, 1399/12/04

Registrant information

Name

Elham Ahmadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3341 3823

Email address

elhamahmadpour10@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of alcoholic extract of the olive leaf on clinical and Laboratory outcomes of patients with Covid-19

Public title
effect of olive leaf extract on Covid-19 patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with Quid-19 based on standard diagnostic test (positive PCR test, CT scan of lung) approved by infectious disease specialist Age range is 18 to 70 years Have a level of consciousness of 15 according to the Glasgow standard
Exclusion criteria:
Take oleopurine supplements 3 months before the study Use of mechanical ventilation equipment Existence of underlying respiratory diseases such as COPD, asthma Taking anti-hypertensive, anti-platelet and anti-diabetic drugs Pregnancy and lactation Immune system deficiency or the use of immunosuppressive drugs Malignancies Presence of heart, kidney, liver, blood pressure, diabetes and corticosteroid disorders Reluctance to continue cooperation The patient is discharged earlier than the completion of the treatment period Hypotension (mean arterial pressure less than 70 mm Hg) Hypoglycemia (blood sugar less than 75 mg / dL) Existence of allergies to drugs before and during the study Lack of proper use of drugs The need for therapeutic interventions other than the usual therapeutic interventions during research such as the need for dialysis, angioplasty and ... Participate in other research that in any way affects the results of the research
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **129**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of samples in study groups by random blocking method
Blinding (investigator's opinion)
Triple blinded
Blinding description
Capsules containing olive leaf extract in two doses of 250 and 500 mg and placebo are exactly the same in terms of color, shape and size and are coded and packaged by another person without the knowledge of the researcher, analyst and participant The contents of the capsule will be placed in the participants' medicine boxes. Before the start of the study and when informed consent is obtained from the participant, they are informed that they are randomly placed in one of the intervention or control groups. Before the start of the study and when informed consent is obtained from the participant, they are informed that they are randomly placed in one of the intervention or control groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences
Street address
University of Medical Sciences, Shahid Anoushirvan Rezaei Square, Moallem St, Khorramabad
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Approval date
2021-02-15, 1399/11/27
Ethics committee reference number
IR.LUMS.REC.1399.262

Health conditions studied

1

Description of health condition studied
COVID - 19
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Arterial oxygen saturation
Timepoint
Before starting the intervention, then for five days twice a day from 6 am to 6 pm
Method of measurement
Medair pulse oximeter device

2

Description
Heart rate
Timepoint
Before starting the intervention, then for five days twice a day from 6 am to 6 pm
Method of measurement
pulse oximeter device

3

Description
Temperatures
Timepoint
Before starting the intervention, then for five days twice a day from 6 am to 6 pm
Method of measurement
Digital thermometer

4

Description
blood pressure
Timepoint
Before starting the intervention, then for five days twice a day from 6 am to 6 pm
Method of measurement
Hand pressure gauge

5

Description
Complete blood count
Timepoint
Before and during the intervention on a daily basis
Method of measurement
Patient file

Secondary outcomes

1

Description
Severity of general symptoms of Covid-19 disease
Timepoint
Before and during the intervention on a daily basis
Method of measurement
Symptom Severity Questionnaire

2

Description
Duration of hospitalization
Timepoint
Patient discharge time
Method of measurement
Counting the number of days the patient is hospitalized

Intervention groups

1

Description
Intervention group: Patients who at the same time with standard treatments, capsules containing olive leaf extract (capsules with a dose of 250 mg twice a day for five days) olive leaf extract by Rose Daru Pharmaceutical Company in drug capsules of the same shape and size as other groups The intervention will be prepared and stored in conditions away from light and moisture.
Category
Treatment - Drugs

2

Description
Intervention group: Patients who at the same time with standard treatments, capsules containing olive leaf extract (capsules with a dose of 500 mg twice a day for five days) olive leaf extract by Rose Daru Pharmaceutical Company in drug capsules of the same shape and size as other groups The intervention will be prepared and stored in conditions away from light and moisture.
Category
Treatment - Drugs

3

Description
Control group: Patients who receive placebo at the same time as standard treatments in the form of capsules containing wheat flour twice a day for five days. The placebo will be stored by Rose Drug Pharmaceutical Company in drug capsules of the same shape and size as the other intervention groups prepared away from light and moisture.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Labbafinejad hospital
Full name of responsible person
Elham Ahmadpour
Street address
Shahid Labbafinejad hospital, 9th Bosthan Alley, Pasdaran St.
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Postal code
1666663111
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elhamahmadpour10@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Ebrahim Fallahi

Street address
University of Medical Sciences, Shahid Anoushirvan Rezaei Square, Moallem St, Khorramabad

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Email
research@lums.ac.ir

Web page address
http://research.lums.ac.ir/index.php?module=web_directory&wd_id=4664

Grant name

Grant code / Reference number

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

Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Elham Ahmadpour

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Student

Latest degree
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Person responsible for updating data

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Position
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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