

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of Trachyspermum copticum-based traditional medicine product on clinical manifestations and Para clinical features in patients with COVID-19: A Randomized clinical trial

Protocol summary

Study aim

The effect of Trachyspermum copticum syrup on clinical presentation and respiratory infection of patients with COVID-19

Design

This is a clinical trial. In this study, there are two groups of control (who receive placebo) and the intervention group (receiving Trachyspermum copticum syrup). The number of people in each group is thirty. The study is triple blind: participants, therapeutic staff, and statistical analyst of data and drugs are blinded.

Settings and conduct

This study is carried out in Valiasr Hospital in Arak. This study is conducted by a researcher and a medical staff in a triple blind manner.

Participants/Inclusion and exclusion criteria

Patients with COVID-19, written and informed satisfaction of patients

Intervention groups

Patients with COVID-19 who have the criteria for entering the study are randomly divided into two groups then, Then for 2 weeks the patients in the intervention group will receive the Trachyspermum copticum syrup and the control group will receive placebo.

Main outcome variables

Respiratory infection

General information

Reason for update

The reason for the update is the modification of the drug manufacturer.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040049N3**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **prospective**

Last update: **2020-04-05, 1399/01/17**

Update count: **1**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Amirhosein Latifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3601

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-05-09, 1399/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Trachyspermum copticum-based traditional medicine product on clinical manifestations and Para clinical features in patients with COVID-19: A Randomized clinical trial

Public title

The effect of Trachyspermum copticum syrup on clinical manifestations of patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to participate in the study
The definitive diagnosis of COVID-19
Failure to attend another clinical trial simultaneously

Exclusion criteria:

Patient's willingness to use other therapies
Alzheimer's patients

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method with 4, 6 and 8 block sizes will be used to assign people to the two groups. Concealment will also be observed by using this method. In this way, each individual is assigned a unique code and is attached to drug packages that will help the blind process.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this three-blind study, patient and therapeutic personnel and data analyst do not have any type of data and medications. The drugs are encoded and placed on the patient and medical personnel.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-03-17, 1398/12/27

Ethics committee reference number

IR.ARAKMU.REC.1398.342

Health conditions studied

1

Description of health condition studied

Patients with Corona Virus

ICD-10 code

U07.1

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Level of CRP in serum

Timepoint

One day before the intervention and one day after the intervention is measured

Method of measurement

Using the ELISA technique

2

Description

The rate of lung inflammation

Timepoint

One day before the intervention and one day after the intervention is measured

Method of measurement

CT SCAN

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" This group consumes the Trachyspermum copticum syrup. The Trachyspermum copticum plant is a member of the Umbrella family. The total extract of this plant is used. The concentration of this syrup is 10% of the aqueous extract of Trachyspermum copticum. This syrup is administered three times daily for two weeks, 5 ml each time, a total of 15 ml daily. The syrup is made by Shahid Beheshti School of Pharmacy.

Category

Treatment - Drugs

2

Description

"Control group:" This group is taking placebo. Placebo syrup have the same size and shape as the drug. The placebo syrup contains all the basic ingredients of a syrup without the addition of herbal medicine. The placebo syrup is made by Shahid Beheshti School of Pharmacy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Valiasr Hospital.

Full name of responsible person

Seied Amirhosein Latifi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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Grant name

Grant code / Reference number

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

No

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Seied Amirhosein Latifi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable