

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of the effectiveness of a Polypodium root preparation on the management of Covid-19 mild to moderate symptoms a clinical trial

Protocol summary

Study aim

Evaluation the effect of Polypodium root preparation on the management of Covid-19 mild to moderate symptoms

Design

A clinical trial with a control group, with parallel groups, single-blinded, randomized, phase 3 will be performed on 40 patients (20 in the intervention group and 20 in the control group) by randomizing the random number table

Settings and conduct

COVID-19 positive rapid test or RT-PCR patients admitted to Ali Asghar Hospital in Shiraz will be divided into two groups of intervention and control. The present study will be double-blind so that patients and physicians will be unaware of how the intervention and control groups assigned.

Participants/Inclusion and exclusion criteria

Patients with COVID-19 positive rapid test or RT-PCR; aged 18 to 70 years with gastrointestinal symptoms

Intervention groups

Intervention group: Iranian standard treatment protocol for COVID-19 in addition to Polypodium oral preparation formulated in Shiraz University of Medical Sciences for 7 days. Control group: the standard treatment protocol of COVID-19 in Iran.

Main outcome variables

clinical symptoms in patients with COVID-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120506009651N4**

Registration date: **2022-06-07, 1401/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-07, 1401/03/17**

Update count: **0**

Registration date

2022-06-07, 1401/03/17

Registrant information

Name

Maryam Mosaffa-Jahromi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-28, 1401/03/07

Expected recruitment end date

2022-11-28, 1401/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of a Polypodium root preparation on the management of Covid-19 mild to moderate symptoms a clinical trial

Public title

Effect of Polypodium in treatment of Coronavirus disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

cases who diagnosed as COVID-19 infection by clinical

features; laboratory findings (positive C Reactive Protein, Chest X-ray findings, CT scan findings) clinical/lab confirmation of the disease hospitalization due to COVID-19 Stated willingness to participate in the study and sign a written informed consent document

Exclusion criteria:

Significant allergic reactions to the herbal drug History of CHF, liver and kidney disorders Patients with diabetes or other endocrine disorders People who are constantly monitored and treated with psychiatric drugs Pregnant/ breast feeding women

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into the treatment and control groups based on simple randomization method and table of random numbers will be used

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher, assessor and data analyst will be blind to the random assignment of patients in groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Shiraz University of Medical Sciences

Street address

7th floor, Shiraz University of Medical Sciences, Zand street

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Shiraz

Province

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Postal code

7134814336

Approval date

2022-05-25, 1401/03/04

Ethics committee reference number

IR.SUMS.REC.1401.160

Health conditions studied

1

Description of health condition studied

COVID-19 infection

ICD-10 code

U07.1

ICD-10 code description

Covid-19, confirmed cases, positive test result

Primary outcomes

1

Description

Clinical/lab confirmation of the disease

Timepoint

Weekly after intervention

Method of measurement

Examination- PCR test

2

Description

Hospitalization due to Covid-19

Timepoint

Weekly after intervention

Method of measurement

Hospital report

Secondary outcomes

1

Description

Improvement of COVID-19 symptoms at end of treatment

Timepoint

End of Treatment (7 days after staring intervention)

Method of measurement

General condition of the patient (clinical symptoms)

Intervention groups

1

Description

Intervention group: Polypodium root decoction (4 grams of herbal powder in 250 ml of boiling water), received twice a day for a week and followed up one week after treatment. In terms of response to treatment, which includes the improvement and reduction of clinical symptoms in COVID-19 patients compared to the pre-treatment status of each patient.

Category

2**Description**

For 7 days, no intervention will be performed on patients in the control group except for the usual treatment protocol. Gastrointestinal symptoms are recorded at the beginning of the study and before treatment, and during 7 days, response to treatment, including improvement and reduction of clinical symptoms in COVID-19 patients, is assessed relative to the pre-treatment status in each patient.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Asghar Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mehdi Zarshenas

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

PhD in Traditional Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Researcher

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Person responsible for updating data

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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