

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3208 4030

###### Email address

mosaffam@sums.ac.ir

##### 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

**City**

Shiraz

**Province**

Fars

**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 starting 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**

Treatment - Drugs

**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

Dr. Mehdi Pasalar

#### Street address

Meshkin Fam Street

#### City

Shiraz

#### Province

Fars

#### Postal code

7143918796

#### Phone

+98 71 3228 8602

#### Email

pasalar@sums.ac.ir

## Sponsors / Funding sources

**1**

### Sponsor

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr. Mahtab Memarpour

#### Street address

Vice Chancellor for Research, Shiraz University of Medical Sciences

#### City

Shiraz

#### Province

Fars

#### Postal code

7134845794

#### Phone

+98 71 3235 7282

#### Email

vcrdep@sums.ac.ir

#### 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

#### Street address

Department of Traditional Pharmact, faculty of Pharmacy, shiraz University of Medical Sciences, Rokn abad street

#### City

Shiraz

#### Province

Fars

#### Postal code

7146864685

#### Phone

+98 71 3242 4128

#### Email

zarm@sums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr. Maryam Mosaffa-Jahromi

#### Position

Researcher

#### Latest degree

Ph.D.

#### Other areas of specialty/work

PhD in Traditional Pharmacy

#### Street address

Research Center for Traditional Medicine and History of Medicine, School of Medicine, Zand Avenue

**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134845794  
**Phone**  
009832084037  
**Email**  
mosaffam@sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Mehdi Pasalar  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Traditional Medicine  
**Street address**  
Research Center for Traditional Medicine and History  
of Medicine, School of Medicine, Zand Avenue  
**City**  
Shiraz  
**Province**

Fars  
**Postal code**  
7134845794  
**Phone**  
009832084029  
**Email**  
pasalar@sums.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