# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jun 2026

## Efficacy of Aniseed powder formulation (Aniseed Safoof) to improve gastrointestinal symptoms in COVID-19 patients

## Protocol summary

**Study aim**
Determining the effect of Aniseed oral powder on clinical improvement of gastrointestinal symptoms in patients with COVID-19

**Design**
Clinical trial with control group, parallel group trial, single-blinded, phase 3 on 225 patients (45 patients in the intervention group and 180 patients in the control group). Replacement randomization was used.

**Settings and conduct**
COVID-19 positive rapid test or RT-PCR patients admitted to Motahari Clinic of Shiraz will be divided into two groups of intervention and control. The present study will be single-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 aniseed oral powder formulated in Shiraz University of Medical Sciences for 2 weeks. Control group: the standard treatment protocol of COVID-19 in Iran.

**Main outcome variables**
gastrointestinal symptoms in patients with COVID-19

## General information

**Reason for update**
Adding achieved recruitment start and end date

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20120506009651N3**
Registration date: **2022-04-04, 1401/01/15**
Registration timing: **prospective**
Last update: **2023-01-11, 1401/10/21**
Update count: **2**

**Registration date**
2022-04-04, 1401/01/15

**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**
2022-03-26, 1401/01/06

**Expected recruitment end date**
2022-09-28, 1401/07/06

**Actual recruitment start date**
2022-05-01, 1401/02/11

**Actual recruitment end date**
2022-08-01, 1401/05/10

**Trial completion date**
2022-08-01, 1401/05/10

**Scientific title**
Efficacy of Aniseed powder formulation (Aniseed Safoof) to improve gastrointestinal symptoms in COVID-19 patients

**Public title**
Effect of Aniseed in treatment of gastrointestinal symptoms in Coronavirus disease

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients from 18 years old to 70 years old with a diagnosis of Coronavirus based on clinical and laboratory symptoms; hospitalization, home quarantine and outpatients Diarrhea, anorexia, nausea or vomiting and abdominal pain within 24-48 hr
**Exclusion criteria:**
Pregnant or nursing females Organic disorders with survival time of less than 3 days Significant allergic reactions to the herbal drug

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

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **225**
Actual sample size reached: **225**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this study, we will use the Restricted randomization method of block randomization. Blockage is usually used to balance the number of samples allocated to each of the studied groups. This feature helps researchers to equalize the number of samples allocated to each of the studied groups in cases where intermediate analyzes are required during the sampling process. All blocks are the same size, and in this two-group experiment we will have 4 blocks (including 1 participants in the intervention group and 3 participants in the control group). Random allocation software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
The 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**
2022-03-02, 1400/12/11

**Ethics committee reference number**
IR.SUMS.REC.1400.859

## 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**
Diarrhea

**Timepoint**
Before and after intervention

**Method of measurement**
Visual analogue scale (VAS) questionnaire which graded from zero (no sign) to 10 (severe sign).

### 2

**Description**
Anorexia

**Timepoint**
Before and after intervention

**Method of measurement**
Visual analogue scale (VAS) questionnaire which graded from zero (no sign) to 10 (severe sign).

**3**

**Description**
Abdominal pain
**Timepoint**
Before and after intervention
**Method of measurement**
Visual analogue scale (VAS) questionnaire which graded from zero (no sign) to 10 (severe sign).

## Secondary outcomes

**1**

**Description**
Gastrointestinal disorders
**Timepoint**
End of Treatment (2 weeks after starting intervention)
**Method of measurement**
Visual analogue scale (VAS) questionnaire

## Intervention groups

**1**

**Description**
Intervention group: Anise edible powder or anise safoof is a combination of anise fruit powder and candy powder. The method of preparation of this drug form is by grinding & sieving techniques and after grinding the components of the formula with the electric mill of Ultra Centrifugal Mill to deliver the drug to the gastrointestinal tract efficiently. This oral powder is formulated in the form of 5 g sachets in the Pharmaceutics Laboratory of Shiraz School of Pharmacy and enters the clinical phase after confirmation of physicochemical and microbial pharmacopoeia tests from the central laboratory of Shiraz University of Medical Sciences. In the clinical phase and at the beginning of the study, patients in the intervention group are instructed to drink the contents of one sachet of anise powder with a glass of water twice a day for two weeks, in addition to the usual treatment protocol. Gastrointestinal symptoms will be recorded at the beginning of the study and before the start of treatment, and during two weeks the response to treatment, including improvement or reduction of gastrointestinal symptoms, diarrhea, anorexia, nausea and abdominal pain compared to the pre-treatment status in each patient is assessed.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: For 2 weeks, 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 two weeks, response to treatment, including improvement or reduction of gastrointestinal symptoms, diarrhea, anorexia, nausea, and abdominal pain, is assessed relative to the pre-treatment status in each patient.
**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Motahari Clinic
**Full name of responsible person**
Dr. Maryam Mosaffa-Jahromi
**Street address**
Namāzī, Karim Khan Zand Blvd
**City**
Shiraz
**Province**
Fars
**Postal code**
7193613111
**Phone**
+98 71 3208 4030
**Fax**
+98 71 3233 8476
**Email**
mosaffam@sums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Mehdi Pasalar
**Street address**
Research Center for Traditional Medicine and History of Medicine, School of Medicine, Zand Avenue
**City**
Shiraz
**Province**
Fars
**Postal code**
7134845794
**Phone**
+98 71 3208 4030
**Fax**
+98 71 3233 8476
**Email**
pasalar@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. 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
**Fax**
+98 71 3233 8476
**Email**
pasalar@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. 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

## 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