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)

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+98 71 3208 4030

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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
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Namāzī, Karim Khan Zand Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
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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