

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of a Persian Natural Medicine Product based on Tahini Oil on Clinical Signs in Suspected Patients with COVID-19

#### Protocol summary

##### Study aim

Determination The Effect of a Persian Natural Medicine Product based on Tahini Oil on Clinical Signs in Suspected Patients with COVID-19

##### Design

Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 1 on 100 patients. SNOSE is used for randomization.

##### Settings and conduct

Patients referring to Ghaem Specialized Clinic in Mashhad, in two groups of intervention and control, in addition to treatment according to protocol, medicine and placebo, which is called 1 and 2; The front and back of the chest will be rubbed; clinical signs will be checked and recorded by phone on days 0, 7, and 14. Participants, clinical caregivers, outcome assessors, data analyzers, and blinders.

##### Participants/Inclusion and exclusion criteria

Patients referred to a specialist center diagnosed with suspected coronavirus infection; criteria for non-entry: pregnant and lactating mothers.

##### Intervention groups

Intervention group; treatment based on the latest national protocol with the use of a combination product of sesame flour and in the control group; treatment based on the latest national protocol and drug use that is packaged in similar cans, will be done

##### Main outcome variables

Fever, chills, olfactory weakness, loss of taste, shortness of breath, fatigue, weakness and myalgia, dyspnea, headache, hospitalization, death of patients

#### General information

##### Reason for update

Date of beginning and end of patients' visits and relocation of patients

##### Acronym

covid-19

#### IRCT registration information

IRCT registration number: **IRCT20140407017169N2**

Registration date: **2020-04-28, 1399/02/09**

Registration timing: **prospective**

Last update: **2021-02-02, 1399/11/14**

Update count: **1**

##### Registration date

2020-04-28, 1399/02/09

#### Registrant information

##### Name

Hossein Mohammadzadeh Moghaddam

##### Name of organization / entity

Traditional Medicine Faculty, Mashhad University of Medical Sciences,

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1855 2188

##### Email address

homm1349@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2020-04-30, 1399/02/11

##### Expected recruitment end date

2020-06-21, 1399/04/01

##### Actual recruitment start date

2020-05-08, 1399/02/19

##### Actual recruitment end date

2020-08-16, 1399/05/26

##### Trial completion date

2020-08-30, 1399/06/09

#### Scientific title

The Effect of a Persian Natural Medicine Product based on Tahini Oil on Clinical Signs in Suspected Patients with

COVID-19

## Public title

Effect of natural from Tahini oil product on corona

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients referred to a specialist center diagnosed by a suspected infectious disease specialist in Corona Have at least three symptoms of fever / chills, clear chest or voice / shortness of breath, cough / sore throat, general weakness / muscle pain, and have a positive CRP blood test and leukopenia.

### Exclusion criteria:

. Pregnant and lactating mothers

## Age

From **15 years** old

## Gender

Both

## Phase

0

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **100**

Actual sample size reached: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

To create a simple random sequence, two-group web-based randomization (www.graphpad.com) will be used, and to hide the random allocation, the closed-sequence envelope method with random sequence (SNOSE) will be used. An accident is recorded on a card and the cards are placed inside the named cleaners in order. In order to maintain random randomness, the numbering on the external surface is done in the same way. Finally, the lids of the letter envelopes are pasted and placed inside the boxes, respectively. At the beginning of the registration of the participants, according to the order of the participants and the conditions of the study, one of them is a special test book or letter.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

Participant Care provider Outcome assessor Data Analyzer

## Placebo

Used

## Assignment

Parallel

## Other design features

100 patients referred to Sidi Special Clinics and Ghaem Hospital of Mashhad University of Medical Sciences, which 1) according to the diagnosis of a suspected infectious disease specialist, are considered to have 19 outpatient treatment indications and 3) have the criteria

to enter the study method. The available sampling will be selected to provide sample size. Accidental allocation of patients to two groups of 50 interventions (treatment based on the latest national protocol dated April 4, 2017 (chloroquine, naproxen and azithromycin) with the use of a combination product of sesame flour and cow butter, which is basically combined and controlled (treatment based on the latest national protocol And the use of pharmaceuticals that will be prescribed in similar cans with the product of the Special Intervention Group of the Control Group. To create a simple random sequence of web-based randomization (www.graphpad.com), two-group and to hide the random allocation, closed envelope method Will be used with random sequencing (SNOSE). Execution of random allocation process by a person other than the team The study will show that patients in both intervention and control groups, in addition to treatment according to the protocol, will apply the ointment and placebo five times a day for four hours in the amount of one tablespoon of jam (2 g) of the combined product on the back and chest. Prescribing medication and medication is blinded by a specialist

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee Gonabad University of Medical Sciences

##### Street address

Street addressGonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

#### Approval date

2020-04-13, 1399/01/25

#### Ethics committee reference number

IR.GMU.REC.1399.014

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19

## Primary outcomes

### 1

#### Description

Fever

#### Timepoint

At the beginning of the study (before the start of the intervention) and 7 and 14 days after the start of intervention.

#### Method of measurement

check list

### 2

#### Description

chills

#### Timepoint

At the beginning of the study (before the start of the intervention) and 7 and 14 days after the start of intervention.

#### Method of measurement

check list

### 3

#### Description

Respiratory rate

#### Timepoint

At the beginning of the study (before the start of the intervention) and 7 and 14 days after the start of intervention.

#### Method of measurement

check list

### 4

#### Description

Inpatient period

#### Timepoint

At the beginning of the study (before the intervention) and 7 and 14 days after the intervention

#### Method of measurement

check list

### 5

#### Description

Death of patients

#### Timepoint

At the beginning of the study (before the intervention) and 7 and 14 days after the intervention

#### Method of measurement

check list

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Patients in the two intervention and control groups, in addition to treatment according to the protocol, will rub the ointment and placebo 2 and 1 times five times a day for four hours in the amount of one tablespoon of jam (2 g) of the combined product on the back and chest.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Seyyedi Hospital Specialized Clinic

##### Full name of responsible person

Ahmadi Reza

##### Street address

West Saba Street. The beginning of Parstar Street

##### City

Mashhad

##### Province

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##### Postal code

99199-91766

##### Phone

+98 51 3840 0001

##### Email

drrezaahmadi17@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Social Development and Health Promotion Research Center

##### Full name of responsible person

Khosravan Shahla

##### Street address

Asian Roadside , Gonabad University of Medical Sciences

##### City

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##### Province

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##### Phone

+98 51 5722 3028

##### Fax

+98 51 5722 0578

##### Email

khosravan@gmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

**Title of funding source**

Social Development and Health Promotion Research Center

**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**

Gonabad University of Medical Sciences

**Full name of responsible person**

Hossein Mohammadzadeh- Moghadam

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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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