

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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)

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+98 51 1855 2188

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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

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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

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West Saba Street. The beginning of Parstar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Social Development and Health Promotion Research Center

Full name of responsible person

Khosravan Shahla

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Asian Roadside , Gonabad University of Medical Sciences

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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

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