Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Eeffect 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
ntervention 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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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
۹۶۹۱۷۹۳۷۱۸
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
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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
Street address
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