

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of functional food mixtures on serum levels of inflammatory cytokines and laboratory findings in patients with covid-19

Protocol summary

Study aim

The effect of functional food mixtures on serum levels of inflammatory cytokines and laboratory findings in patients with covid-19

Design

Two-blind randomized clinical trial with parallel groups with a sample size of 30 people in each group Random number table was used for randomization.

Settings and conduct

The study will be performed on 60 patients with metabolic syndrome referred to Baqiyatallah Al-Azam Hospital who will be randomly assigned to the intervention and control groups. Patients in the intervention and placebo groups will receive 30 grams of healthy food or 30 grams of regular food (barley soup) after meals for 1 week daily. The researcher and participants will be blind to randomization and assignments until the end of the study.

Participants/Inclusion and exclusion criteria

Among the patients referred to Baqiyatallah Al-Azam Hospital, they will be diagnosed with Covid-19 by doctors according to international standards. Among people with Covid-19 who agree to participate in the study (age 20-70) will enter the study. People on special diets or HIV patients Cancer patients undergoing chemotherapy Immunized patients Patients in need of hospitalization in the intensive care unit of patients with uncontrolled heart, kidney or Liver of pregnant or lactating women

Intervention groups

Patients in the intervention group will receive 30 grams of functional food daily in the morning for 1 week. Control group: Patients in the control group will receive 30 grams of plain barley soup daily for 1 week as a placebo at the same time and as a snack.

Main outcome variables

The amount of inflammatory and anti-inflammatory cytokines (IL-1 β , IL-6, TNF α , IL-10, IL-4 , IFN γ)

General information

Reason for update

Completion of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20180201038585N11**

Registration date: **2021-08-23, 1400/06/01**

Registration timing: **prospective**

Last update: **2022-11-05, 1401/08/14**

Update count: **1**

Registration date

2021-08-23, 1400/06/01

Registrant information

Name

Karim Parastouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 3516

Email address

parastouei@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-05, 1400/06/14

Expected recruitment end date

2022-01-04, 1400/10/14

Actual recruitment start date

2021-09-20, 1400/06/29

Actual recruitment end date

2022-01-14, 1400/10/24

Trial completion date

2022-05-09, 1401/02/19

Scientific title

Effect of functional food mixtures on serum levels of inflammatory cytokines and laboratory findings in patients with covid-19

Public title

Effect of functional food mixtures on serum levels of inflammatory cytokines in patients with covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The need for hospitalization with clinical signs in favor of coronavirus infection includes one or more of the following : The patient experiences a decrease in oxygen saturation of less than 93% A drop in systolic blood pressure less than 100 or a drop in blood pressure of 30 mm Hg from the patient's previous normal systolic pressure fever Dry cough the positive result of CRP index Laboratory indexes included : CRP , ESR

Exclusion criteria:

Patient dissatisfaction Lack of proper conditions for oral feeding

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using groups of 4 (blocks) that were similar in terms of sex and age by a random number table and trained by a third person and assigned to intervention and control groups to receive one of the treatments. Concealment was also performed using sealed envelopes so that researchers and participants were unaware of the allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, regular food and functional food will be placed in the same 30 grams sachets. The sachets are then placed in paper boxes and will receive a special code from the label company. Ordinary and functional food codes will remain with the company until the end of the study to blind researchers, laboratory staff, and patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Mollasadra st Ave, Vannak Sq

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2021-05-10, 1400/02/20

Ethics committee reference number

IR.BMSU.REC.1399.149

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

The amount of inflammatory and anti-inflammatory cytokines (IL-1 β , IL-6, TNF α , IL-10, IL-4 ,IFN γ)

Timepoint

At the start and after 1 week of study

Method of measurement

Through intravenous blood samples and commercial kits

Secondary outcomes

1

Description

Laboratory findings

Timepoint

At the beginning and after 1 week of study

Method of measurement

Through intravenous blood samples and commercial kits

Intervention groups

1

Description

Intervention group: At the beginning of the study, patients in the intervention group will receive 30-gram sachets of functional food (functional soup). Patients in the intervention group will be asked to consume a 30-gram packet of functional food (functional soup) daily in the morning for 1 week. In order to increase compliance, patients were asked on a daily basis.

Category

Treatment - Other

2

Description

Control group: Patients in the control group will receive 30-gram packages of regular food (barley soup) at the beginning of the study. Patients in the control group will be asked to consume a 30-gram packet of regular food (barley soup) daily in the morning for 1 week. In order to increase compliance, patients are asked on a daily basis.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah University of Medical Sciences

Full name of responsible person

Karim Parastouei

Street address

Sheikh bahaei Ave , Molasadra st

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5470

Fax

Email

parastouei@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Ali Shiri

Street address

Baqiyatallah University of Medical Sciences, sheikh bahaei Ave, Mollasadra st

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5250

Email

research@bmsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Karim Parastouei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Baqiyatallah University of Medical Sciences, sheikh bahaei Ave, Mollasadra st

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5470

Email

parastouei@bmsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Karim Parastouei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Baqiyatallah University of Medical Sciences, sheikh bahaei Ave, Mollasadra st

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5470

Email

parastouei@bmsu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Yahya Jalilpiran

Position

Ph.D candidate

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Baqiyatallah University of Medical Sciences, sheikh bahaei Ave, Mollasadra st

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5470

Email

Yjalilpiran@razi.tums.ac.ir

Web page address**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