Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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-1β، Il-6، TNFα ، IL-10، IL-4 ، IFNγ)

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)

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+98 21 8248 3516

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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-1β، Il-6، TNFα،IL-10، IL-4 ,IFNγ)

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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

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Person responsible for scientific inquiries

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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