

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of simultaneous administration of biotin, brewer's yeast, and vitamin C supplements on the improvement of clinical symptoms in patients with COVID-19

Protocol summary

Study aim

Due to the role of biotin, brewer's yeast, and vitamin C in improving the symptoms of diseases such as influenza and cold, the aim of the present study is to evaluate the effect of these supplements on the improvement of clinical symptoms associated with COVID-19.

Design

The clinical trial consists of a control group with parallel, non-blind, randomized, phase 3 on 50 patients and, a random number table will be used for randomization.

Settings and conduct

In this study, 50 male patients who have referred to Shariati Hospital with a positive chest CT scan for COVID-19 will be selected. After completing the consent form and questionnaire, patients will be divided randomly into two groups according to inclusion and exclusion criteria. In addition to their routine treatment, one group will receive three biotin tablets (5000 micrograms) on the first day, two biotin tablets (5,000 micrograms) on the second and third day, and one biotin tablet (5,000 micrograms) on the fourth to eighth days. In addition to biotin, one effervescent tablet of vitamin C (500 mg) and two tablets of brewer's yeast for 10 days will be received, daily. The control group will receive only routine Covid-19 treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 to 60 years; Male sex; Patients whose chest CT scan is positive for COVID-19; Exclusion criteria: Infectious diseases, cancer, and autoimmune diseases; Severe heart and liver diseases; Existence of severe clinical symptoms that require; hospitalization; Diabetes

Intervention groups

In addition to routine treatment, the intervention group will receive biotin, brewer's yeast, and vitamin C supplements for 10 days. The control group will have its own routine treatment.

Main outcome variables

Clinical symptoms improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201004048923N1**

Registration date: **2020-12-13, 1399/09/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-13, 1399/09/23**

Update count: **0**

Registration date

2020-12-13, 1399/09/23

Registrant information

Name

Shadi Seyyed Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6405 3293

Email address

ebrahimi_sh@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-15, 1399/07/24

Expected recruitment end date

2021-01-14, 1399/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of simultaneous administration of biotin, brewer's yeast, and vitamin C supplements on the improvement of clinical symptoms in patients with COVID-19

Public title
Effect of biotin, brewer's yeast and vitamin C supplements in patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 60 years old Male sex COVID-19 patients with positive chest CT scan
Exclusion criteria:
Infectious diseases, cancer and autoimmune diseases Severe heart and liver diseases Existence of severe clinical symptoms that require hospitalization Diabetes

Age
From **20 years** old to **60 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The stratification layer in this study is age. In order to allocate the same number of people in both groups, stratified randomization was used. Randomization of individuals into intervention and control groups was performed using a random number list created online by Random.org. This list is randomly divided between intervention and control groups from 1 to 50.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address
Building No 1, Tehran university of Medical Sciences, Poursina St. Qods St. Enqelab St

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2020-09-30, 1399/07/09

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.574

Health conditions studied

1

Description of health condition studied

Coronavirus disease 2019 (COVID-19)

ICD-10 code

U07. 1

ICD-10 code description

U07. 1

Primary outcomes

1

Description

Clinical symptoms improvement

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

Secondary outcomes

1

Description

Fever

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

2

Description

Chills

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

3**Description**

Fatigue

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

4**Description**

Cough

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

5**Description**

Shortness of breath

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

6**Description**

Headache

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

7**Description**

Myalgia

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in

the checklist

8**Description**

Earache

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

9**Description**

Rhinorrhea

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

10**Description**

Sore throat

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

11**Description**

Diarrhea

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

12**Description**

Nausea or vomiting

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

13

Description

Swelling

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

14

Description

Skin allergy

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

15

Description

Paleness of the fingers and toes

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

16

Description

Smell or taste loss

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

17

Description

Chest pain or discomfort

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

18

Description

Loss of the ability to move or speak

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

19

Description

Insomnia

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

20

Description

Sweating

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

21

Description

Anorexia

Timepoint

At the beginning of the study (before the intervention) and after receiving supplements, daily

Method of measurement

Patient statements during the phone call and recording information according to the scoring system designed in the checklist

Intervention groups

1

Description

Intervention group: Patients in this group, addition to their routine treatment will receive; first day: two biotin tablets (5000 micrograms) simultaneously and after that with at least 6 hours, one another biotin tablet (5000 micrograms), second and third days: two biotin tablets (5,000 micrograms) with at least 8 hours interval. Fourth day up to the end of intervention: one biotin tablet (5,000 micrograms) daily. In addition to biotin, one effervescent tablet of vitamin C (500 mg) and two tablets of brewer's yeast will be received, daily up to the end of intervention.

Category

Treatment - Drugs

2

Description

Control group: Control group will receive only routine COVID-19 treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital Emergency

Full name of responsible person

Dr Maliheh Paknejad

Street address

Biochemistry department, Tehran university of Medical Sciences, Poursina St. Qods St. Enqelab St

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 6405 3295

Email

paknejadma@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Maliheh Paknejad

Street address

Biochemistry department, Tehran university of Medical Sciences, Poursina St. Qods St. Enqelab St

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 6405 3295

Email

paknejadma@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

By researcher

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Maliheh Paknejad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Biochemistry department, Tehran university of Medical Sciences, Poursina St. Qods St. Enqelab St

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 6405 3295

Email

paknejadma@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Maliheh Paknejad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Biochemistry department, Tehran university of Medical Sciences, Poursina St. Qods St. Enqelab St

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 6405 3295

Email

paknejadma@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Dr Maliheh Paknejad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Biochemistry department, Tehran university of
Medical Sciences, Poursina St. Qods St. Enqelab St

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 6405 3295

Fax**Email**

paknejadma@tums.ac.ir

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

Yes - There is 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

Title and more details about the data/document

Undecided - It is not yet known if there will be a plan to
make this available

When the data will become available and for how long

Undecided - It is not yet known if there will be a plan to
make this available

To whom data/document is available

Undecided - It is not yet known if there will be a plan to
make this available

Under which criteria data/document could be used

Undecided - It is not yet known if there will be a plan to
make this available

From where data/document is obtainable

Undecided - It is not yet known if there will be a plan to
make this available

What processes are involved for a request to access data/document

Undecided - It is not yet known if there will be a plan to
make this available

Comments