

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Investigating the effect of vitamin B1 oral tablets on the post covid-19 syndrome in comparison with the control group

Protocol summary

Study aim

Investigating the effect of vitamin B1 on the symptoms of post covid-19 syndrome

Design

A clinical trial with a control group, with a parallel group, randomized on 60 patients, rand function of Excel software was used for randomization.

Settings and conduct

60 patients of Labafinejad Hospital who are eligible entered the study and were divided into two groups of 30 people, the treatment group and the control group.

Participants/Inclusion and exclusion criteria

A patient who is eligible to enter the study (patients who have recovered from the disease of Covid-19, but their symptoms still persist more than usual, after three weeks of the onset of the symptoms of Covid-19, they also have symptoms such as fatigue, sleep disorders, decreased sense of taste and smell , etc.) Criteria for not entering the study: pregnant women, patients who use antipsychotic drugs, and patients with immunodeficiency

Intervention groups

Control group receives only supportive therapy (vitamin C, Famotidine, and Zinc) daily for 8 weeks. Intervention group receives vitamin B1 tablet (600 mg) daily for 8 weeks, in addition to the supportive therapy.

Main outcome variables

Sleep quality, Hair loss, Skin rashes, Dyspnea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221229056979N1**

Registration date: **2023-05-31, 1402/03/10**

Registration timing: **retrospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

Elmira Mahmoudi Chalmiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4203 0898

Email address

dr.elmira_1991@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

2022-03-21, 1401/01/01

Actual recruitment end date

2023-03-21, 1402/01/01

Trial completion date

2023-06-21, 1402/03/31

Scientific title

Investigating the effect of vitamin B1 oral tablets on the post covid-19 syndrome in comparison with the control group

Public title

Investigating the effect of vitamin B1 oral tablets on the post covid-19 syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All Patients who have recovered from covid 19 but after three weeks the symptoms of post covid 19 syndrome remain

Exclusion criteria:

Pregnancy Immune deficiency patients Patients who use antipsychotic drugs

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

First, 60 patients who are eligible to enter the study (patients who have recovered from the disease of covid-19, but their symptoms are still more than usual, after three weeks of the onset of symptoms of covid-19, have symptoms such as fatigue, sleep disorders, loss of sense of taste and smell, chest pain, cough, joint pain, hair loss, skin rashes, etc.) are at the time of admission background information including sex, age, clinical and drug records, disease manifestations and laboratory findings as well as symptoms Vitality and severity of the disease, history of hospitalization and receiving corticosteroids will be collected from the patients and recorded in the study checklist. Then for the patients of the treatment group (30 people) who will be randomly selected.

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 Shahid Beheshti University of Medical Sciences

Street address

School of medicine of Shahid Beheshti University of medical sciences, Koodakyar Ave., Daneshjoo Blvd., Yaman St., Chamran highway.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.SBMU.MSP.REC.1400.286

Health conditions studied

1

Description of health condition studied

Post covid-19 syndrome

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Sleep quality

Timepoint

Patients will be examined weekly during 9 weeks and the checklist will be completed for them.

Method of measurement

Questionnaire

2

Description

Hair loss

Timepoint

Patients will be examined weekly during 9 weeks and the checklist will be completed for them.

Method of measurement

Questionnaire

3

Description

Skin rashes

Timepoint

Patients will be examined weekly during 9 weeks and the checklist will be completed for them

Method of measurement

Questionnaire

4

Description

Dyspnea

Timepoint

Patients will be examined weekly during 9 weeks and the checklist will be completed for them

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Quality of life score

Timepoint

Patients will be examined weekly during 9 weeks and the checklist will be completed for them.

Method of measurement

Questionnaire

Intervention groups

1

Description

Control group: Control group receives only supportive therapy including vitamin C, Famotidine, and Zinc (one tablet for each supplement) orally for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group receives vitamin B1 (600 mg daily for 8 weeks) in addition to supportive therapy (same as control group).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labafinezhad hospital

Full name of responsible person

Shabnam Tehrani

Street address

9th Boostan St., Pasdaran, Tehran

City

Tehran

Province

Tehran

Postal code

1666663111

Phone

+98 21 2360 2085

Email

dr.elmira_1991@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, No. 2, Arabi St., Yemen St., Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 9780

Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shabnam tehrani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Zafar

City

Tehran

Province

Tehran

Postal code

1919753973

Phone

+98 21 2360 2084

Email

dr.elmira_1991@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shabnam tehrani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Zafer

City

Tehran

Province

Tehran

Postal code

1919753973

Phone

+98 21 2360 2084

Email

dr.elmira_1991@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shabnam tehrani

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

Street address

Zafar

City

Tehran

Province

Tehran

Postal code

1919753973

Phone

+98 21 2360 2084

Email

dr.elmira_1991@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Part of the data, such as information related to the main outcome or similar, can be shared

When the data will become available and for how long

The beginning of the access period from 1402

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Data for clinical use will be available

From where data/document is obtainable

dr.elmira_1991@yahoo.com

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

After the request, the data will reach the requester within a week.

Comments