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 immundefitiency
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
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Iran (Islamic Republic of)
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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.

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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
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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
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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
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Shabnam tehrani
Position
Associate professor
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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