

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Assessment of boron-containing compounds and oleoylethanolamide supplementation on the recovery trend in Patients with COVID-19: A double-blind randomized placebo-controlled clinical trial

Protocol summary

Study aim

Assessment of boron-containing compounds and Oleoylethanolamid Supplementation on recovery trend in Patients with Known COVID-19

Design

Randomized clinical trial with parallel group trial, double-blinded ,first phase carried out on 40 Covid-19 patients. Randomization was carried out with rand function at an excel software.

Settings and conduct

Patients were randomly divided into 4 groups. The first group receive two capsule containing 5 mg boron compounds per day ,The second group receive two capsule containing 200 mg Oleoylethanolamide per day ,The third group receive two capsule containing 5 mg boron compounds with 200 mg Oleoylethanolamide per day and the fourth group receive two placebo tablets. the participants and researchers were blinded for intervention types during the study period.The groups will be compared in terms of patient recovery rate and hospital admission rate, vital signs and biochemical parameters such as CBC, ESR, CRP before and after the intervention.

Participants/Inclusion and exclusion criteria

Patients with Known COVID-19

Intervention groups

1. Receiving boron containing compound supplement:daily 2 capsules including 5 mg boron containing compound for two weeks
- 2.Receiving oleoylethanolamide supplement:daily 2 capsules including 200 mg oleoylethanolamide for two weeks
3. Receiving oleoylethanolamide and boron containing compound supplement:daily 2 capsules including 200 mg oleoylethanolamide and 5 mg boron for two weeks
4. Receiving placebo: daily 2 capsules including starch

Main outcome variables

recovery rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090609002017N35**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

ostadrahimi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-19, 1399/02/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of boron-containing compounds and oleoylethanolamide supplementation on the recovery trend in Patients with COVID-19: A double-blind randomized placebo-controlled clinical trial

Public title

Assessment of boron-containing compounds and Oleoylethanolamid supplementation in the treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Known COVID-19

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals with inclusion criteria divided into intervention and control groups using Random allocation software (RAS).

Blinding (investigator's opinion)

Double blinded

Blinding description

The intervention and control groups individuals and main researcher do not know the type of supplements.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Nutrition Research Center, Faculty of Health and Nutrition, Tabriz University of Medical Sciences,

Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.TBZMED.REC.1399.099

Health conditions studied

1

Description of health condition studied

COVID - 19

ICD-10 code

U07.01

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Recovery trend

Timepoint

At baseline and at the end of intervention

Method of measurement

Examination

2

Description

Hospital admission time

Timepoint

At baseline and at the end of intervention

Method of measurement

Observation

3

Description

CBC,ESR

Timepoint

At baseline and at the end of intervention

Method of measurement

Blood sampling and testing with H1 device

4

Description

CRP

Timepoint

At baseline and at the end of intervention

Method of measurement

Blood sampling and measurement with Auto analyzer device

Secondary outcomes

empty

Intervention groups

1

Description

Group 1 consume 2 capsules containing 5 mg boron containing compound per day for two weeks.

Category

Treatment - Drugs

2

Description

Group 2 consume 2 capsules containing 200 mg oleoylethanolamide per day for two weeks

Category

Treatment - Drugs

3

Description

Group 3 consume 2 capsules containing 5 mg boron containing compound and 200 mg oleoylethanolamide per day for two weeks

Category

Treatment - Drugs

4

Description

Group 4 as a control group consume 2 placebo capsules containing starch powder per day for two weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Alireza Ostadrahimi

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Imam Reza Hospital, University Street, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

All data are resulting from Research project and will be used just for manuscript printing in academic journals.

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable