

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 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

##### Street address

Imam Reza Hospital, University Street, Tabriz, Iran

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3347 0549

##### Email

info@darctbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Alireza Ostadrahimi

##### Street address

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

##### City

Tabriz

##### Province

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##### Postal code

5166614711

##### Phone

+98 41 3335 2292

##### Email

nut-rc@tbzmed.ac.ir

#### 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

##### Street address

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

##### City

Tabriz

##### Province

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Alireza Ostadrahimi

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Professor

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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