

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 2026

Survey the effect of magnesium citrate supplementation on clinical symptoms and TNF- α and hs-CRP factors in patients with COVID-19

Protocol summary

Study aim

In this study, the effect of magnesium citrate on COVID-19 will be examined.

Design

A clinical trial with control group including a sample size of 60 people, with parallel group, double-blind, randomized

Settings and conduct

This study is a randomized, double-blind, placebo-controlled trial, which the researcher and participants will be blinded by encoding magnesium citrate and placebo by the other person. The subjects are hospitalized patients with COVID-19 at Razi hospital in Ahvaz, which will have the inclusion criteria to enter the study. The participants will be randomized through the statistical method of permuted block. Blocks will be determined using statistical software.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 65 years : Laboratory confirmation of Covid-19 (2019-nCoV Real-Time RT-PCR)

Intervention groups

Patients in both groups receive the treatment based on the Covid-19 National Guidelines. Patients in the intervention group, in addition to the standard treatment protocol, receive magnesium citrate supplement in the form of 300 mg capsules once a day for 1 month. And the control group also receives placebo containing starch according to the above method.

Main outcome variables

Cough : Oxygen saturation : Respiratory rate : Fever :
Rate of lung involvement : Duration of hospitalization :
hs-CRP : TNF- α : CBC : Final status of the patient :
Depression : Anxiety : Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210413050957N1**

Registration date: **2021-05-01, 1400/02/11**

Registration timing: **prospective**

Last update: **2021-05-01, 1400/02/11**

Update count: **0**

Registration date

2021-05-01, 1400/02/11

Registrant information

Name

Sepideh Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3441 2049

Email address

sepidehrostami.nutrition@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of magnesium citrate supplementation on clinical symptoms and TNF- α and hs-CRP factors in patients with COVID-19

Public title

Survey the effect of magnesium citrate supplementation on clinical symptoms and TNF- α and hs-CRP factors in patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Laboratory confirmation of Covid-19 (2019-nCoV Real-Time RT-PCR) Patients with moderate status Age from 18 to 65 years gender: male/female
Exclusion criteria:
 Hospitalization of the patient in the intensive care unit Underlying diseases such as diabetes, hypertension, cardiovascular disease, kidney disease and mental disorders such as depression Obesity (BMI $\geq$ 30) Vitamin D level less than 30 ng / ml Hypomagnesemia (magnesium level less than 1.7 mg / dL) and hypermagnesemia (magnesium level higher than 2.6 mg / dL) Pregnancy and lactation Contraindications, intolerance or allergy to magnesium Taking dietary supplements Alcohol and drug abuse

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning the intervention to individuals is random and the randomized permutation blocks with block size 4 (using the table related to random permutations). The randomization list is prepared by a statistician. The supplement and placebo used in this study, according to the randomized list, will be placed in closed envelopes by a person outside the study who does not know the research objectives and according to the corresponding codes.

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher and participants are blinded by coding the drug in the form of A and B, so that someone else is asked to encode the magnesium citrate and placebo to A and B which are similar in appearance. The participants and the researcher will be uninformed of the type of intervention. As a result, the study will be performed in the forms of double blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2021-04-12, 1400/01/23

Ethics committee reference number

IR.AJUMS.REC.1400.025

Health conditions studied

1

Description of health condition studied

covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified.

Primary outcomes

1

Description

Cough

Timepoint

First and 30 days after the intervention

Method of measurement

Clinical examination

2

Description

Oxygen saturation

Timepoint

First and 30 days after the intervention

Method of measurement

using pulse oximeter device

3

Description

Respiratory rate

Timepoint

First and 30 days after the intervention

Method of measurement

Clinical examination

4**Description**

Fever

Timepoint

First and 30 days after the intervention

Method of measurement

Clinical examination

5**Description**

Rate of lung involvement

Timepoint

First and 30 days after the intervention

Method of measurement

CT scan of the chest

6**Description**

Duration of hospitalization

Timepoint

First and 30 days after the intervention

Method of measurement

Counting the days of hospitalization

7**Description**

hs-CRP

Timepoint

First and 30 days after the intervention

Method of measurement

Based on laboratory measurements-mg/l

8**Description**TNF- α **Timepoint**

First and 30 days after the intervention

Method of measurement

Based on laboratory measurements-mg/l

9**Description**

CBC

Timepoint

First and 30 days after the intervention

Method of measurement

Cell counter

10**Description**

Final status of the patient

Timepoint

First and 30 days after the intervention

Method of measurement

Dead / Alive

11**Description**

Depression

Timepoint

First and 30 days after the intervention

Method of measurement

questionnaire scoring(BDI-II)

12**Description**

Anxiety

Timepoint

First and 30 days after the intervention

Method of measurement

questionnaire scoring(STAI)

13**Description**

Quality of Life

Timepoint

First and 30 days after the intervention

Method of measurement

questionnaire scoring(sf-36)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The magnesium citrate supplement is taken as a 300 mg capsule once a day for 1 month.

Category

Treatment - Drugs

2**Description**

Control group: The placebo is taken as a capsule containing 300 mg starch once a day for 1 month.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi hospital

Full name of responsible person

Sepideh Rostami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz 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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Sepideh Rostami
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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

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available