Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ≥ 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
Street address
Felestin Ave., Amanieh Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mehdi Ahmadi Moghadam
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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
Position
Student
Latest degree
Master
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Person responsible for updating data

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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