Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Comparing the effect of standard treatment with and without vitamin A supplementation in improving the clinical symptoms of outpatients with COVID-19

Protocol summary

Study aim

Comparison of the effects of vitamin A supplementation with standard therapies in the treatment of outpatients with COVID-19

Design

A control trial with a control group, with a parallel groups, double-blind, randomized, phase 3 group on 140 patients that will be randomized using block method and Random Allocation software.

Settings and conduct

This study is performed in Amir Al-Momenin Hospital in Arak. Blinding is a double-blind type and will be done using a placebo. In this way, patients will be blind to the clinical caregiver, outcome assessor, and data analyzer, recognizing groups based solely on the letters A and B.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having clinical signs and test results confirming COVID-19; CRP level higher than 0.3 mg per liter; ESR higher than 22 mm per hour for women and 29 mm per hour for men. Exclusion criteria: Having any autoimmune disease (lupus, MS, etc.); Suffering from diseases that interfere with the absorption of vitamin A; patients with severe renal insufficiency and dialysis; lactation and pregnancy

Intervention groups

Control group: they receive only the national standard treatment and a placebo drug similar to the main drug. Intervention group: In addition to the standard treatment recommended in the national protocol, they will receive 25,000 international units of vitamin A orally per day for 10 days.

Main outcome variables

Clinical symptoms improvement, Hospitalization rate, Paraclinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210102049912N1**
Registration date: **2021-04-07, 1400/01/18**
Registration timing: **prospective**

Last update: **2021-04-07, 1400/01/18**
Update count: **0**

Registration date

2021-04-07, 1400/01/18

Registrant information

Name

mehdi shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3630

Email address

dr_mehdi75@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of standard treatment with and without vitamin A supplementation in improving the clinical symptoms of outpatients with COVID-19

Public title
The effect of vitamin A supplementation in outpatients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having clinical signs and test results that confirm COVID-19 CRP level higher than 0.3 mg per liter Having an ESR higher than 22 mm per hour for women and 29 mm per hour for men

Exclusion criteria:
Having any autoimmune disease (lupus, MS, etc.) Suffering from diseases that interfere with the absorption of vitamin A. Consumers of vitamin A supplements Patients with severe renal insufficiency and dialysis Patients with underlying liver disease Pregnancy Lactation

Age
From **15 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization is performed using block generation method and Random Allocation software. Random Allocation software provides a table of 140 in which our two groups, groups A and B, are each repeated 70 times randomly to minimize the possibility of biased intervention. Each cell in this table is called a block. There will be one patient in each block and the therapist will refer the patients who meet the inclusion criteria to the pharmacy and the patients will be placed in the random blocks of the above table, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be a double-blind study using placebo. Therefore, in order to blind in this study, patients, laboratory technicians, therapist who will be responsible for the activity of prescribing drugs, receiving samples and completing a questionnaire, as well as the researcher responsible for evaluating the results and statistical analyzer will be blind to patient allocation, and will not know which patient is in the intervention and which patient is in the control group. The main researcher will not be blind to the groups and will prepare the drugs and placebo in two packages A and B and place them in the pharmacy with the pharmacist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Payambar-e-azam Complex, Sardasht Town

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2020-07-25, 1399/05/04

Ethics committee reference number
IR.ARAKMU.REC.1399.162

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
Clinical symptoms improvement

Timepoint
Before the intervention and 10 days after the start of the intervention

Method of measurement
Definition of clinical improvement includes normalization of body temperature (≤37.2's,) number of breaths (≤ 24 breaths per minute,) oxygen saturation (> 94% at room temperature) that is stable for at least 24 hours

2

Description
Hospitalization
Timepoint
Ten days after the start of the intervention
Method of measurement
Patients' hospitalization will be recorded using a questionnaire and their follow-up.

3

Description
C-reactive protein
Timepoint
Before the intervention and 10 days after the intervention
Method of measurement
Hemagglutination

4

Description
Erythrocyte Sedimentation Rate
Timepoint
Before the intervention and 10 days after the intervention
Method of measurement
Erythrocyte Sedimentation test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to receiving the national standard treatment, patients will receive oral vitamin A 25,000 international units (Zahravi-Iran) per day for 10 days.
Category
Treatment - Drugs

2

Description
Control group: In the control group, patients receive only the national standard treatment with an oral placebo similar to the main drug, once a day for 10 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al-Momenin Hospital
Full name of responsible person
Mehdi Shokri
Street address
Basij Sq., Sardasht Town
City
Arak
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Markazi
Postal code
3848176941
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+98 86 3417 3630
Email
dr_mehdi75@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Basij Sq., Sardasht Town
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3848176941
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Email
research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Mehdi Shokri
Position

Internist

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Position

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data

When the data will become available and for how long

from 2021

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Therefore, obtaining permission for all processes is free

From where data/document is obtainable

Arak University of Medical Sciences

What processes are involved for a request to access data/document

Email the researcher and receive the file.

Comments