

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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 ( $\leq 37.2^{\circ}\text{C}$ ), number of breaths ( $\leq 24$  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

#### **Province**

Markazi

#### **Postal code**

3848176941

#### **Phone**

+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

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3848176941

##### **Phone**

+98 86 3417 3630

##### **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  
**Street address**  
Payambar-e-azam Complex, Sardasht Town  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
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**Position**

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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