

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Comparison of the effectiveness of standard treatment with stand treatment plus Vitamin A in treatment in covid19 patients

#### Protocol summary

##### Study aim

Determining and comparing the effectiveness of standard treatment with standard treatment plus vitamin A in the treatment of patients with covid 19

##### Design

In a controlled double-blind trial, a parallel plan of 140 patients will be randomly assigned to the experimental (70 subjects) and control (70 subjects) groups and will be followed for 10 days.

##### Settings and conduct

70 experimental group patients in Saveh will receive vitamin A, in addition to the standard treatment recommended for COVID 19 in the national protocol. Patients with COVID-19 in the control group will receive standard national treatment and placebo. Before and after treatment, the rate of recovery in both experimental and control groups is measured. The patients will be randomly allocated to the experimental group or the control group. In this study, they will be blind: laboratory technicians and radiologists, the therapist who was responsible for prescribing the drug, receiving the sample and completing the questionnaire, and the researcher responsible for evaluating the results and analyzing Statistics on group therapy of patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 1-75 years Exclusion criteria: Autoimmune diseases (lupus, MS, etc.), Hepatit B, C, vitamin A supplement users, pregnant and lactating women

##### Intervention groups

The experimental group will receive a standard medical protocol, in addition to which vitamin A will be taken orally by 25,000 IU/day for ten days. The control group will receive the standard medical protocol and plasebo.

##### Main outcome variables

Clinical: body temperature, number of breaths, oxygen saturation ) and cough. Paraclinical: changes in CRP levels, and lymphocytes before and after treatment, ESR, CBC diff, CPK, LDH, blood pH,o2 sat, creatinine and LFT

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180520039738N2**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **retrospective**

Last update: **2020-04-10, 1399/01/22**

Update count: **0**

##### Registration date

2020-04-10, 1399/01/22

##### Registrant information

##### Name

Mohamadreza Rohani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4460 4118

##### Email address

mohamadreza.rohani@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-07, 1399/01/19

##### Expected recruitment end date

2020-04-07, 1399/01/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effectiveness of standard treatment with stand treatment plus Vitamin A in treatment in covid19 patients

#### Public title

Evaluation and comparison of the effectiveness of standard treatment with stand treatment plus Vitamin A in treatment in covid19 patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Covid 19 patients Age over one year Age less than 75 years Tendency to participate in research Completion of informed written consent

##### Exclusion criteria:

pregnant women lactating women hepatitis B, C Autoimmune diseases Chronic renal failure (CRF) Liver failure Congestive heart failure (CHF) Chronic obstructive pulmonary disease (COPD)

#### Age

From **1 year** 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

At the beginning of the study, an evaluator examines the criteria for entering the study of patients, and if there are conditions for entering the study, using the table of random numbers, patients will be assigned to the experimental and control group. And this process will continue until the formation of two equal groups of 70 people.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study, patients, laboratory technicians, radiologists, and therapists who will be responsible for prescribing the drug, receiving the sample and completing the questionnaire, as well as the researcher responsible for evaluating the results and statistically analyzing the treatment group will blind patients. Were, and will not know the intervention group. The physicians responsible for prescribing medication will not be blind. vitamin A and placebo were purchased from the same factory and coded by the third person who is not involved in the study. the patients have received the random code by the secretariat who is not involved in the study. the patients with even numbers will receive the capsules from box A and the patients with odd numbers will receive the capsules from box B. To make a

placebo, Since Zahrawi Vitamin A will be used for the experimental group, the control group will also use Zahrawi's placebo drug to make the placebo look and feel similar to the original vitamin A, but the active ingredient will be an ineffective substance.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Saveh University of Medical Sciences

##### Street address

Yas street, Kaveh industrial city, Saveh

##### City

Saveh

##### Province

Markazi

##### Postal code

3941617698

#### Approval date

2020-04-03, 1399/01/15

#### Ethics committee reference number

IR.SAVEHUMS.REC.1399.003

## Health conditions studied

### 1

#### Description of health condition studied

Corona virus disease 2019 (COVID-19)

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

body temperature

#### Timepoint

before the start of the intervention and 10 days after the supplement Vitamin A

#### Method of measurement

Measuring body temperature with a thermometer through the mouth

## 2

### **Description**

Blood oxygen saturation percentage

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Pulse oximeter

## 3

### **Description**

Cough rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Physical examination

## 4

### **Description**

C-Reactive Protein (CRP) Test rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## 5

### **Description**

Complete blood count (CBC) Rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## 6

### **Description**

Creat. Rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## 7

### **Description**

lymphocytes Rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## 8

### **Description**

Erythrocyte Sedimentation Rate (ESR) rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## 9

### **Description**

Number of breaths

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Physical examination

## 10

### **Description**

The pH of the blood

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## 11

### **Description**

Creatine phosphokinase (CPK) rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## 12

### **Description**

Lactate Dehydrogenase (LDH) rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## 13

### **Description**

Liver function tests rate

### **Timepoint**

Before and ten days after starting treatment

### **Method of measurement**

Laboratory

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group:25000 IU vitamin A per day for ten days, the plus, the standard national treatment for COVID 19

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: the standard national treatment for

COVID19 ,and placebo  
**Category**  
Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Dr Mozaffar's office

**Full name of responsible person**

Hasan Mozaffar

**Street address**

No.2, Morvarid Doctors Building., Enghelab street.,  
Saveh

**City**

Saveh

**Province**

Markazi

**Postal code**

3941946637

**Phone**

+98 86 4221 4138

**Email**

hassan.mozaffar@gmail.com

### 2

#### Recruitment center

**Name of recruitment center**

Mostafakhomeini medical center

**Full name of responsible person**

Dr, Mohammad Ghorbanli

**Street address**

No.12, Mostafakhomeini medical center., Shariati  
Street, Saveh

**City**

Saveh

**Province**

Markazi

**Postal code**

3941945539

**Phone**

+98 86 4223 8874

**Email**

karimymahmood6686@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Saveh University of Medical Sciences

**Full name of responsible person**

Dr., Hamidreza Koohestani

**Street address**

No.10, Yas st, 15th Ave, Kaveh Industrial City, Saveh,  
Saveh University of medical science

**City**

Saveh

**Province**

Markazi

**Postal code**

3914334911

**Phone**

+98 86 4234 3396

**Email**

koohestani709@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Saveh 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**

Saveh University of Medical Sciences

**Full name of responsible person**

Mohammadreza Rouhani

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No.4, Shahid Shiroodi St. - Alam Al-Huda St., Arak  
University of Medical Sciences, School of Medicine,  
Department of Internal Medicine

**City**

Arak

**Province**

Markazi

**Postal code**

۳۸۱۹۶۹۳۳۴۰

**Phone**

+98 86 3368 4615

**Email**

mohamadreza.rohani@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mohamadreza Rohani

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Shahid Shiroodi St. - Alam Al-Huda St., Arak University of Medical Sciences, School of Medicine, Department of Internal Medicine

**City**

Arak

**Province**

Markazi

**Postal code**

۳۸۱۹۶۳۳۴۰

**Phone**

+98 86 3368 4615

**Email**

mohamadreza.rohani@yahoo.com

3914334911

**Phone**

+98 86 4234 3395

**Email**

karimymahmood@yahoo.com

**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**

Yes - There is 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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

By publishing an article

**When the data will become available and for how long**

Access started on September 2020

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Scientific and therapeutic

**From where data/document is obtainable**

Mohamad Reza Rohani, 00989122859099, mohamadreza.rohani@yahoo.com

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

72 hours after a phone call or email

**Comments**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Saveh University of Medical Sciences

**Full name of responsible person**

Mahmood Karimy

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Yas st, 15th Ave, Kaveh Industrial City, Saveh, Markazi Province, Iran

**City**

Saveh

**Province**

Markazi

**Postal code**