

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Oct 2020

### The effect of supplementation with vitamin A on improvement of symptoms of acute respiratory syndrome in patients with COVID-19: A randomized clinical trial

#### Protocol summary

##### Study aim

Given the anti-inflammatory role of vitamin A, the aim of the present study was to investigate the effect of vitamin A supplementation on the symptoms of acute respiratory syndrome in patients with COVID-19.

##### Design

Phase 3 clinical trial with control group on 120 patients, without blinding, randomized by random numbers table.

##### Settings and conduct

Clinical trials will be conducted at Firoozgar Medical Training Center affiliated to Iran University of Medical Sciences in Tehran on patients admitted with COVID-19. Patients are treated in two groups: intervention and control. The study will be performed at the beginning of hospitalization. At the end of the study, the information of two groups of patients will be blindly provided to the statistical analyst.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 80-18 years; Desire for participate to the project. Non-inclusion criteria: Severe liver and biliary disease and known pancreatitis; History of vitamin A supplementation last month; Pregnancy; Breastfeeding.

##### Intervention groups

Individuals in the intervention group receive 50,000 IU of vitamin A through injection, daily, for 10 days in addition to routine treatment, and the control group receives only routine treatment.

##### Main outcome variables

Weaning time from ventilator

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200405046951N1**

Registration date: **2020-06-11, 1399/03/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-11, 1399/03/22**

Update count: **0**

##### Registration date

2020-06-11, 1399/03/22

##### Registrant information

###### Name

Azadeh Mottaghi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8603 6080

###### Email address

mottaghi.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-08-21, 1399/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of supplementation with vitamin A on improvement of symptoms of acute respiratory syndrome in patients with COVID-19: A randomized clinical trial

**Public title**

Vitamin A and COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being at the age of 18-80 years old The same treatment protocol Desire to participate in project

**Exclusion criteria:**

Severe liver and biliary disease and known pancreatitis  
History of vitamin A supplementation last month  
Pregnancy Lactation

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using a table of random numbers, patients will be assigned to intervention and control groups, and this process will continue until two groups of 60 people are formed.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic committee of Iran University of Medical Sciences

**Street address**

Research Vice Chancellor of Iran University of Medical Sciences, Next to blood transfusion organization, Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2020-05-05, 1399/02/16

**Ethics committee reference number**

IR.IUMS.REC.1399.204

**Health conditions studied****1****Description of health condition studied**

Covid-19

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Weaning time of ventilator

**Timepoint**

Before and after of intervention

**Method of measurement**

time assessment

**Secondary outcomes****1****Description**

Rapid shallow breathing index (RSBI)

**Timepoint**

before and after intervention

**Method of measurement**

ventilator

**2****Description**

Pao2/Fio2 ratio

**Timepoint**

before and after intervention

**Method of measurement**

ventilator

**3****Description**

Fraction of inspired oxygen (FiO2)

**Timepoint**

before and after intervention

**Method of measurement**

ventilator

**4****Description**

oxygen saturation

**Timepoint**

before and after intervention

**Method of measurement**

ventilator

## Intervention groups

1

### Description

Intervention group: receiving Vitamin 50000 IU through injection

### Category

Treatment - Drugs

2

### Description

Control group: Routine care

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Firoozgar hospital

#### Full name of responsible person

Azadeh Mottaghi

#### Street address

Behafarin aveue, Karimkhan street

#### City

Tehran

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#### Phone

+98 21 8603 6080

#### Email

mottaghi.azadeh@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Dr. Amir Abbas Motevalian

#### Street address

Hemmat highway

#### City

Tehran

#### Province

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#### Postal code

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#### Phone

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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

Iran 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

Iran University of Medical Sciences

#### Full name of responsible person

Azadeh Mottaghi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

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Hemmat highway

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Azadeh Mottaghi

#### Position

Assistant Professor

#### Latest degree

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#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Azadeh Mottaghi  
**Position**  
Assistant Professor  
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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

Undecided - It is not yet known if there will be 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

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