

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 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

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Behafarin aveue, Karimkhan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Amir Abbas Motevalian

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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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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

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