

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 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

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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 Measureing 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.,
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2

Recruitment center

Name of recruitment center

Mostafakhomeini medical center

Full name of responsible person

Dr, Mohammad Ghorbanli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Saveh University of Medical Sciences

Full name of responsible person

Dr., Hamidreza Koohestani

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No.10, Yas st, 15th Ave, Kaveh Industrial City, Saveh,
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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

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

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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

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