Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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)

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+98 21 4460 4118

Email address
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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., Saveh

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Province

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2

Recruitment center

Name of recruitment center

Mostafakhomeini medical center

Full name of responsible person

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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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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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Subspecialist

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Latest degree
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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