

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Assessment of vitamin A effectiveness on COVID-19 patients and treatment outcomes referred to health centers of Qom province

Protocol summary

Study aim

Evaluation of the effectiveness of vitamin A on the clinical symptoms of COVID-19 disease, including the duration of fever, cough and shortness of breath, and on laboratory factors such as CPR, white blood cells, and creatinine.

Design

Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 2 on 94 patients. The rand function of the Excel software was used for randomization

Settings and conduct

All patients admitted to Kamkar Hospital underwent a three-way blind course and were prescribed vitamin A and placebo.

Participants/Inclusion and exclusion criteria

Admission: Start treatment within the first three days of hospitalization Failure to enter: Pregnant women and those with high cerebrospinal fluid pressure

Intervention groups

There are two intervention and control groups, which are given to the vitamin A intervention group, and the placebo control group is basically a three-way blind

Main outcome variables

Treatment and prevention of primary and secondary complications of COVID_19 disease, including: pulmonary fibrosis, cerebral edema, renal failure, secondary bacterial infections and mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200314046774N1**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-12, 1399/03/23**

Update count: **0**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

Majid Farhadi fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3662 0845

Email address

majidfarhadifard@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-06-13, 1399/03/24

Actual recruitment start date

2020-05-04, 1399/02/15

Actual recruitment end date

2020-06-13, 1399/03/24

Trial completion date

2020-06-13, 1399/03/24

Scientific title

Assessment of vitamin A effectiveness on COVID-19 patients and treatment outcomes referred to health centers of Qom province

Public title

treatment of COVID-19 whit vitamin A

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All adult patients were hospitalized with covid_19 who were hospitalized for at least the first three days

Exclusion criteria:

Pregnant women who with high cerebrospinal fluid pressure People with malnutrition (celiac disease, short bowel syndrome, chronic pancreatitis, and impaired fat and anti-obesity and bariatric surgery)

Age

From **1 year** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **94**

Actual sample size reached: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 100 patients with covid 19 will be randomly divided into two groups. The selection of groups will be based on the fact that individuals will be assigned to groups based on block randomization. Block size 4 is considered. So we will have four blocks of four, including AB, AAB, BAAB, ABBA, BABA, BBAA, AB. The selection of each block will also be random and will be done using dice. For example, if the number 3 comes in the dice roll, the BBAA block is considered, so the first two patients are treated with B and the next two patients with A treatment. The dice will be thrown 25 times to complete the allocation of patients to treatment groups. Also, treatment allocation to groups A and B will be based on accident (coin toss).

Blinding (investigator's opinion)

Triple blinded

Blinding description

The statistical physician only had access to medical information, and the nurse, physician, and patient were blind. On the box of real and placebo drugs, codes were written by a statistician and epidemiologist, and the drugs were given to patients by accident, but the doctor, nurse, and patient were unaware of their contents. The codes were provided to the physician

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of qom University of Medical Sciences

Street address

No10,alley 2, avenue13, emam khomeini street, qom,iran

City

qom

Province

Ghoum

Postal code

3718913997

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.MUQ.REC.1399.045

Health conditions studied

1

Description of health condition studied

covid-19

ICD-10 code

U07.1

ICD-10 code description

Use this code when COVID-19 has been confirmed by laboratory testing irrespective of severity of clinical signs or symptoms. Use additional code, if desired, to identify pneumonia or other manifestations.

Primary outcomes

1

Description

rate of O2 saturation

Timepoint

1-3-5-7-10-14

Method of measurement

PCR, CT scan and clinical symptoms

2

Description

clinical symptoms

Timepoint

1-3-5-7-10-14

Method of measurement

PCR, CT scan and clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: "Consumption of Iranian Oral Vitamin A in the name of Ovigel Company 200,000 units today and repeat it tomorrow and then control the clinical and laboratory symptoms on the first, third, fifth, seventh, fourteenth and fourteenth days. Check the test: INR, LDH, wBC, PLT, LYMPH, CRP, CPK, Cr, Hb n need mechanical ventilation to check vitamin A side effects

Category

Treatment - Drugs

2

Description

Control group: receives exactly four in appearance similar to the vitamin A capsule (drug Gul) and the next day the same thing is repeated and then the control of clinical symptoms and Laboratory test on the first, third, fifth, seventh, fourteenth, fourteenth day of the test: INR, LDH, wBC, PLT, LYMPH, CRP, CPK, Cr, Hb n.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom Kamkar hospital

Full name of responsible person

Majid Farhadifard

Street address

No 10, Alley 2, Avenue 13, Emam Khomeini street, Qom, Iran

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Ghous

Postal code

3718913997

Phone

+98 25 3662 0845

Email

Majidfarhadifard@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Dr. Kohpayehee

Street address

No 83, Alley 4, Alley 1/1, Safashahr street

City

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Province

Ghous

Postal code

37169934567

Phone

+98 25 3285 4011

Email

reserch@mail.mcq.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Majid Farhadifard

Position

پزشک عمومی

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No 10, Alley 13, Avenue Emam Khomeini, Qom, Iran

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Part of the data is accessible

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Phone call with Dr. Majid FarhadiFard at 09127521134

From where data/document is obtainable

Phone call with Dr. Majid FarhadiFard at 09127521134

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

Phone call with Dr. Majid FarhadiFard at 09127521134

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Majid Farhadifard

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