

# 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

##### City

Qom

##### Province

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

Qom

##### 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

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Majid Farhadifard

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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**

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