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

Update count: 0
Registration date: 2020-06-12, 1399/03/23
Registrant information
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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, AABB, 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**

**Health conditions studied**

1. **Description of health condition studied**
   - covid-19

2. **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

2. **Timepoint**
   - 1-3-5-7-10-14

**Method of measurement**
- PCR, CT scan and clinical symptoms

**Secondary outcomes**

**Intervention groups**
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

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 day of the test: INR, LDH, wBC, PLT, LYMPH, CRP, CPK, Cr, Hb n.

Category
Placebo

Recruitment centers

Recruitment center
Name of recruitment center
Qom Kamkar hospital
Full name of responsible person
Majid Farhadifard
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Sponsors / Funding sources

Sponsor
Name of organization / entity
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Person responsible for general inquiries
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Ghoum University of Medical Sciences
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Majid Farhadifard
Position
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Grant name
Ghoum University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Country of origin
Academic
Person responsible for updating data

Contact
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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