

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

evaluation the effect of vitamin A on respiratory signs and hospitalization in patients with COVID-19

Protocol summary

Study aim

Determination of the effect of vitamin A on respiratory sign and hospitalization duration in patients with COVID-19

Design

two arm, parallel group randomized controlled trial

Settings and conduct

This study will be conducted in Imam Reza hospital, affiliated with Tabriz University of medical sciences. based on inclusion criteria 30 patients will be selected and respiratory signs and saturation rate will be recorded at the first day of hospitalization. then the patients will randomly divided to two groups of 15 patients. in vitamin A group, the patients will receive 50000 dose of vitamin A along with routine treatments and in the control group, The patients will receive only the routine treatments. after two weeks the respiratory sign, saturation rate and hospitalization days will be recorded

Participants/Inclusion and exclusion criteria

Inclusion criteria: confirmed diagnosis of COVID-19 with RT-PCR; hospitalized patients; ventilator independent patients; Exclusion criteria: being pregnant; lactating mothers; not consent to participate in the study; using high-dose vitamin A in last month.

Intervention groups

Vitamin A group will include 15 patients with COVID-19 that will be treated with vitamin A 50000 along with routine treatment for two weeks Control group will also include 15 patients with COVID-19 that will be treated with only routine treatment for two weeks

Main outcome variables

Hospitalization duration respiratory signs

General information

Reason for update

according to PIs recommendation the respiratory sign were reported as clinical response.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170117032004N3**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **prospective**

Last update: **2020-09-29, 1399/07/08**

Update count: **1**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Zeinab Nikniaz

Name of organization / entity

Liver and gastrointestinal disease research center, Tabriz University of medical sciences-Tabriz_Ir

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 7473

Email address

nikniazz@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation the effect of vitamin A on respiratory signs and hospitalization in patients with COVID-19

Public title

Effect of vitamin A in patients with COVID19

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

confirmed diagnosis of COVID19 with RT-PCR hospitalized patients ventilator independent patients

Exclusion criteria:

being pregnant, lactating mothers, not consent to participate in the study using high-dose vitamin A in last month

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

simple random allocation using computer by a person who is not one of researcher of the study and based on the numbers allocated to each patients.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of medical sciences

Street address

Tabriz University of medical sciences, Daneshgah Ave.Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2020-03-16, 1398/12/26

Ethics committee reference number

IR.TBZMED.REC.1398.1305

Health conditions studied**1****Description of health condition studied**

U07.1

ICD-10 code

07.1

ICD-10 code description

Confirmed cases

Primary outcomes**1****Description**

clinical response

Timepoint

until discharge from hospital

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

hospitalization period

Timepoint

at the end of study

Method of measurement

medical record review

2**Description**

mechanical ventilation need

Timepoint

During the study

Method of measurement

medical record review

Intervention groups**1****Description**

Intervention group: 50000 Vitamin A daily for two weeks

Category

Treatment - Other

2**Description**

Control group: common treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Zeinab Nikniaz

Street address

Imam Reza Hospital, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 1688

Email

znikniaz@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Sameiee

Street address

Tabriz University of medical sciences, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 7310

Email

lgdrc2005@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zeinab Nikniaz

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Liver and gastrointestinal diseases research center, Imam Reza Hospital, Tabriz University of medical sciences, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 1688

Email

znikniaz@hotmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zeinab Nikniaz

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Imam Reza hospital, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41133351688

Fax**Email**

znikniaz@hitmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zeinab Nikniaz

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Imam Reza Hospital, Tabriz University of medical sciences, Tabriz_Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3336 7473

Fax**Email**

nikniazz@tbzmed.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Not decided

When the data will become available and for how long

Not decided

To whom data/document is available

Not decided

Under which criteria data/document could be used

Not decided

From where data/document is obtainable

Not decided

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

Not decided

Comments