Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effectiveness of omega-3 and Hydroxychloroquine on Inflammatory factors, liver enzymes and clinical symptoms in diabetic COVID-19 patients

Protocol summary

Study aim

Determination of the efficacy of omega-3 fatty acids on inflammatory markers, liver enzymes and clinical symptoms in patients with Covid-19.

Design

Randomized clinical trial with parallel control group, single blind (outcome assessor), phase 1, 30 patients, using stratified randomization.

Settings and conduct

The current trial was performed on diabetic patients with Covid-19 in Amir-Alam hospital in Tehran. The aim and protocol of the study were described for participants. Patients were randomized to intervention or control group. The study was single-blind in which the outcome assessor was not aware about each patient's group. Before supplementation information about patients including anthropometric indices and physical activity were collected. Moreover, blood sampling and assessment of clinical symptoms including pain, appetite, olfactory and fatigue were conducted at the baseline and end of the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI ≥18.5 - age≥18 - Diabetic patients diagnosed with covid-19 according to the decision of the relevant physician- Not consuming any particular diet or supplement as well as not doing any particular physical activity - having tendency to participate in our study Exclusion criteria: Having inflammatory disorders including liver, kidney or thyroid abnormalities, pancreatitis, any malignancy –receiving omega-3 supplements - Pregnancy - Lactating - Menopause - smoking or alcohol intake - having any abnormality in PTT, PT or INR tests

Intervention groups

Intervention group: omega-3 (670 mg EPA and DHA) + 400 mg Hydroxychloroquine. Control group: 400 mg Hydroxychloroquine.

Main outcome variables

Erythrocyte Sedimentation Rate (ESR) and C-reactive protein, alanine aminotransferase (ALT), aspartate amino transferase (AST) and alkaline phosphatase (ALKP) and clinical symptoms including fatigue, body pain, appetite and smelling problem.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200511047399N1**
Registration date: **2020-07-23, 1399/05/02**
Registration timing: **retrospective**

Last update: **2020-07-23, 1399/05/02**
Update count: **0**

Registration date

2020-07-23, 1399/05/02

Registrant information

Name

Hamed Abdollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 3352

Email address

h-abdollahi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of omega-3 and Hydroxychloroquine on Inflammatory factors, liver enzymes and clinical symptoms in diabetic COVID-19 patients

Public title

Effect of omega-3 on diabetic patients with Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body mass index equal to or more than 18.5 age equal to or more than 18 Diabetic patients diagnosed with covid-19 according to physician diagnosis Not consuming any particular diet or supplement as well as not doing any particular physical activity Willingness to participate in the study

Exclusion criteria:

Having a history or current diagnosis of inflammatory disorders including liver, kidney or thyroid abnormalities, pancreatitis, any malignancy or other conditions that impact inflammatory status Patients who had regularly received omega-3 supplements during 3 months before our trial Pregnancy Lactating Menopause Patients with history of smoking (at-least 5 cigarette per day) or alcohol intake during 6 months before our trial any abnormality in PTT, PT or INR tests

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified Randomization method was used to control gender and BMI variables. BMI is considered normal (BMI= 18.5- 24.9) and abnormal (BMI≥ 25) and gender is considered as male and female, and thus four lists including women with normal BMI, women with abnormal BMI, men with normal BMI and men with abnormal BMI were considered. Patients were then divided into 2 groups by Permuted Block Randomization. In each separate list, the two-block modes (AB, BA) will be randomly assigned to each treatment order using a random number table. In each list, the order of treatment is determined and therefore, using the double blocks defined according to the random table, patients are placed in equal numbers in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

the current study is a single-blinded clinical trial, in which the outcome assessor is not aware of each participant's group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences: No. 226, Poursina St., Qods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.TUMS.VCR.REC.1399.440

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.2

ICD-10 code description

COVID-19, virus not identified

Primary outcomes

1

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

In the baseline of the study and after 2 weeks supplementation with omega-3

Method of measurement

Automated erythrocyte sedimentation rate analyzer

(ELECTA LAB S.r.l, Via Balzella, Italy)

2

Description
C-reactive protein
Timepoint
In the baseline of the study and after 2 weeks supplementation with omega-3
Method of measurement
Immunoturbidimetric method (Pars Azmun, Iran)

3

Description
Fatigue
Timepoint
In the baseline of the study and after 2 weeks supplementation with omega-3
Method of measurement
Self-reported questionnaire with sores ranging from 1 until 10

4

Description
Body pain
Timepoint
In the baseline of the study and after 2 weeks supplementation with omega-3
Method of measurement
Self-reported questionnaire with sores ranging from 1 until 10

5

Description
Appetite
Timepoint
In the baseline of the study and after 2 weeks supplementation with omega-3
Method of measurement
Self-reported questionnaire with sores ranging from 1 until 10

6

Description
Olfactory
Timepoint
In the baseline of the study and after 2 weeks supplementation with omega-3
Method of measurement
Self-reported questionnaire with sores ranging from 1 until 10

Secondary outcomes

1

Description
Alanine aminotransferase
Timepoint
In the baseline and after 2 weeks omega-3 supplementation
Method of measurement
Available valid diagnostic test kits (Crest Biosystems kits, India)

2

Description
Aspartate aminotransferase
Timepoint
In the baseline and after 2 weeks omega-3 supplementation
Method of measurement
Available valid diagnostic test kits (Crest Biosystems kits, India)

3

Description
alkaline phosphatase
Timepoint
In the baseline and after 2 weeks omega-3 supplementation
Method of measurement
Available valid diagnostic test kits (Crest Biosystems kits, India)

Intervention groups

1

Description
Intervention group: 3 capsules containing 2010 mg EPA and DHA + 2 capsules containing 400 mg Hydroxychloroquine
Category
Treatment - Drugs

2

Description
Control group: 2 capsules containing 400 mg Hydroxychloroquine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir A'lam Hospital
Full name of responsible person
Hamed Abdollahi
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Amir A'lam Hospital., Saadi street., Enghelab Street., Tehran., Iran
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Tehran 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable