

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation the Effect of Coconut Oil as a complementary therapy on fatigue in Covid-19 patients A randomized double-blind pilot study

Protocol summary

Study aim

Determining the effect of coconut oil supplement therapy in improving weakness and reducing the duration of patients with Covid-19

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 28 patients. Random sequence generator software was used for randomization

Settings and conduct

Patients in Mashhad who are being treated at home with a diagnosis of Covid19 are randomly selected and placed in one of two control or intervention groups. Both groups are treated according to the standard protocol of the Ministry of Health. The intervention group, consumes 30 cc (15 cc every 12 hours) of virgin coconut oil daily in pure form or with milk or soup and The control group receives 30 cc (15 cc every 12 hours) of the placebo solution (pure or with milk or soup) daily. Demographic information, weakness and other symptoms (shortness of breath, cough, fever, sore throat, myalgia, etc.) are recorded by a VAS-based questionnaire at the beginning and one week after treatment by the researcher by phone. They followed up at the end of the second week for symptoms.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 80 years who, according to the information registration system of Mashhad University of Medical Sciences, have been diagnosed with Covid 19 and are under care and treatment at home, Criteria for non-inclusion include: patients with allergies to coconut and its derivatives, severe illness, and need for hospitalization

Intervention groups

The intervention and control groups receive routine treatment of the disease. In addition, the intervention group consumed 30 cc (15 cc every 12 hours) of coconut oil daily in their diet orally (pure or with milk or soup). The control group consumes the placebo solution with

the same instructions.

Main outcome variables

Weakness according to VAS criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200418047125N1**

Registration date: **2021-08-06, 1400/05/15**

Registration timing: **retrospective**

Last update: **2021-08-06, 1400/05/15**

Update count: **0**

Registration date

2021-08-06, 1400/05/15

Registrant information

Name

Ghazaleh Ghorbannezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5224 2670

Email address

ghorbannezhadg962@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the Effect of Coconut Oil as a complementary therapy on fatigue in Covid-19 patients A randomized double-blind pilot study

Public title
The effect of coconut oil consumption on improving the weakness of COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients 18-80 years old have been diagnosed COVID-19, According to the information registration system of Mashhad University of Medical Sciences hospitalized at home
Exclusion criteria:
 History of Allergy to coconut and its derivatives
 Dissatisfaction with inclusion in the study Severe illness and need for hospitalization

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization will be performed by simple randomization method using random numbers derived from Excel program. First, the total sample size and number of groups are entered into the software. The software output includes a list that randomly assigns patients to two groups A (intervention) and B (control). Patients are distributed according to the time of referral according to the list of the mentioned group until the end of sampling. Random sequence generation in Excel software is done using the RANDBETWEEN () function According to this method, each of the cells is randomly assigned a code of 0 or 1. Cells with code 0 belong to the intervention group and cells with code 1 belong to the control group. Patients are assigned to one of the groups according to the generated list.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is performed as a double-blind study. The researcher and the patients participating in the study are unaware of the content of the drug. Drugs are prepared and coded in similar packages and provided to the executor for the prescription to patients. The outcome

assessment is done by a person who is blind to the allocation process.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Mashhad University of Medical Sciences
Street address
 School of Medicine, Mashhad University of Medical Sciences,Vakilabad St., Mashhad
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9138813944
Approval date
 2021-04-24, 1400/02/04
Ethics committee reference number
 IR.MUMS.REC.1400.023

Health conditions studied

1

Description of health condition studied
COVID- 19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
weakness

Timepoint
End of the first and second week

Method of measurement
According to the VAS criteria

Secondary outcomes

1

Description

fever
Timepoint
At the end of the first and second week
Method of measurement
Thermometer

2

Description
Intensity and frequency of cough
Timepoint
At the end of the first and second week
Method of measurement
Visual Scale Scoring or VAS

3

Description
myalgia
Timepoint
At the end of the first and second week
Method of measurement
Visual Scale Scoring or VAS

4

Description
respiratory rate
Timepoint
At the end of the first and second week
Method of measurement
count respiratory rate in one minute

5

Description
Hospitalization
Timepoint
At the end of the first and second week
Method of measurement
The ratio of the number of cases leading to hospitalization to the total number of patients in each group

Intervention groups

1

Description
Intervention group: In addition to routine treatment, 30 cc (every 12 hours 15 cc) of virgin coconut oil is consumed orally in pure form or with milk or soup. Routine treatment includes acetaminophen 500 mg tablets every 8 In case of pain or fever, take one vitamin 1000 microgram tablet daily and recommend rest, proper nutrition, and adequate fluid intake.
Category
Treatment - Drugs

2

Description
Control group: In addition to routine treatment, patients

in the control group consume 30 cc (15 cc every 12 hours) of placebo solution (containing mineral water + coconut flavoring) in pure form or with milk or soup. Routine treatment includes acetaminophen 500 mg tablets every 8 In case of pain or fever, take one vitamin 1000 microgram tablet daily and recommend rest, proper nutrition, and adequate fluid intake.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
second grade COVID-19 centers in Mashhad
Full name of responsible person
Alireza Derakhshan
Street address
Akhund Khorasani24, Imam Ali Covid-19 center
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3852 8185
Fax
Email
tim.pr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafghodi piyade gheibi
Street address
Mashhad, University Street, Ghorashi Building
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vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Ghazaleh Ghorbannezhad

Position

Medical Student

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

Street addressNo. 4, Emad khorasani 7, piroozi 72, piroozi Blvd,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Ali Reza Derakhshan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street addressMashhad, University of Medical Sciences, Faculty of
Iranian and Complementary Medicine**City**

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

Mashhad University of Medical Sciences

Full name of responsible person

Ghazaleh Ghorbannezhad

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Email

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/documentInformation and data on the primary and secondary
outcomes of patients will be shared after being
identified.**When the data will become available and for how long**Ability to access data about 6 months after printing the
results**To whom data/document is available**All researchers will be allowed access to the data after
reviewing it by the person in charge of the study.**Under which criteria data/document could be used**Any analysis of the data will be possible only with the
permission of the corresponding author

From where data/document is obtainable

corresponding Author

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

The person submits their request, the corresponding author evaluates the accessibility and if possible the access to the data will be granted.

Comments