Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Fax

Email

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 address
No. 4, Emad khorasani 7, piroozi 72, piroozi Blvd, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9179973148
Phone
+98 51 3891 8263
Email
ghorbannezhadg962@mums.ac.ir

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 address
Mashhad, University of Medical Sciences, Faculty of Iranian and Complementary Medicine
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3884 8931
Email
Derakhshanar@mums.ac.ir

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
Street address
University of Medical Sciences, Faculty of Medicine, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Email
ghorbannezhadg962@mums.ac.ir

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/document
Information 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