

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Investigating the effects of oral medium-chain triglyceride (MCT) on the process of disease symptoms in patients with viral respiratory tract infection in outpatients with metabolic syndrome

Protocol summary

Study aim

Determining the effect of moderate oral triglyceride administration on the course of symptoms in outpatients with viral respiratory tract infection with metabolic syndrome

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 3 on 80 patients. Random Allocation Software was used for randomization.

Settings and conduct

First, patients referred to viral respiratory tract infection and metabolic syndrome are identified to Afzalipour Medical Center within a 6 months. Then they enter the study based on entry and exit criteria and based on random sampling and after obtaining informed consent. At this stage, their demographic information will be recorded and the drug will be studied and the relevant training will be provided to them. Body temperature, number of breaths per minute, rate of body pain, cough and side effects using a questionnaire that the patient must fill in on days zero (referral time) 1, 2, 3, 4, 7, 14 to both groups of intervention and Controls are evaluated.

Participants/Inclusion and exclusion criteria

Admission Requirements: Metabolic Syndrome as defined by the International Diabetes Federation (IDF) Non-entry conditions: Allergy to the drug Pregnancy / breastfeeding Asthma and allergies Congestive heart failure Chronic renal failure Malignancy Immune system defects

Intervention groups

Intervention group: Administration of oral medium-chain triglyceride at a dose of 2 tablespoons after each meal and daily recording of symptoms Control group: daily recording of symptoms

Main outcome variables

Cough intensity; Number of coughs; Breathing speed; body pain; Fever; death; Hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201019049079N1**

Registration date: **2021-07-03, 1400/04/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-03, 1400/04/12**

Update count: **0**

Registration date

2021-07-03, 1400/04/12

Registrant information

Name

Mohammad Amin Fallah Mehrizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3325 7660

Email address

amin.fallah44@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of oral medium-chain triglyceride (MCT) on the process of disease symptoms in patients with viral respiratory tract infection in outpatients with metabolic syndrome

Public title

MCT Oil in viral respiratory tract infection in patient with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Metabolic Syndrome as defined by the International Diabetes Federation (IDF): Abdominal obesity above 94 cm in men and 80 cm in women plus two of the following criteria: IFG above 100, triglyceride above 150, HDL below 40 in men and below 50 in women And have systolic blood pressure above 130 mmHg or diastole above 85 mmHg Symptoms of viral respiratory tract infection

Exclusion criteria:

Drug allergy Pregnancy / breastfeeding Asthma and allergies CHF CRF malignancy Immune system defects such as AIDS and corticosteroids

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Random Allocation Software, patients are randomly divided into intervention and control groups. The samples will be determined by random blocking method with 4 blocks and using the table of random numbers of Software Allocation Random software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research (Allocation Concealment. The sample allocation ratio will be 1: 1 Allocation and will be placed in two groups receiving Iranian medicine products and control (Assignment. Will be given The study is Lable-Open and blinding will not happen.

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 Afzalipoor Hospital of Kerman Medical University

Street address

pajooresh square

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.KMU.AH.REC.1400.047

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B97.29

ICD-10 code description

Other coronavirus as the cause of diseases classified elsewhere

2

Description of health condition studied

Seasonal Influenza

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Adult Cold

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Symptoms of viral respiratory tract infection (fever, cough, body aches, shortness of breath)

Timepoint

Days 0 (visit day) ,1,2,3,4,7 and 14

Method of measurement

Questionnaire and question from the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To determine the effect of the substance mentioned in the text of Take 2 tablespoons of Medium-Chain Triglyceride oil after each meal for 7 days, and after this Action The healing process was examined chemical formula: Triglyceride with two or three fatty acids having an aliphatic tail of 6-12 carbon atoms. This drug is not produced in the country.

Category

Treatment - Drugs

2

Description

Control group: No special intervention is performed. (Except filling out the questionnaire)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipoor hospital

Full name of responsible person

Hamid Abosaidi

Street address

Pajooresh Square

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Kerman

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Kerman

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98 34 3121 5600

Phone

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Email

amin.fallah44@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Somayeh Crossroads (Tahmasb Abad) at the beginning of Ibn Sina Street, Deputy of Research and Technology

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Kerman

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7619813159

Phone

+98 34 3226 3855

Email

vcr@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Amin Fallah Mehrizi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Masoud Moghadari

Position

Deputy Director of Management and Resources

Development
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mohammad Amin Fallah Mehrizi
Position
Student
Latest degree
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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

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

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

Measured variables are available after unidentifiable individuals.

When the data will become available and for how long

Up to one year after publish results.

To whom data/document is available

All people in the research centers.

Under which criteria data/document could be used

Allowed for any use.

From where data/document is obtainable

Mohammad Amin Fallah, 09135258850,
amin.fallah44@gmail.com

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

After contacting and knowing the identity of the person, information will be provided to them.

Comments