Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of L-carnitin as an adjunctive therapy in treatment of negative and positive symptom in schizophrenia

Protocol summary

Study aim
1- To improve positive and negative symptoms in patients with schizophrenia 2- To reduce the profile of fats, reduce cardiovascular diseases, improve the metabolism of fats in patients with schizophrenia, 3- To reduce the cost of treatment of diseases caused by the effects of metabolic disorders and the effects of drug treatment.

Design
Clinical trial with control group, parallel group, double-blind, randomized, phase 3 on 60 patients, four-way randomization block method was used for randomization.

Settings and conduct
In this study, after the preparation of L-carnitine and placebo medicine, which no one except the drug maker (plan manager, nurse, patient caregivers) knows about, is given to patients admitted to Quds Hospital in Sanandaj or care centers in Sanandaj city.

Participants/Inclusion and exclusion criteria
1- Not having severe major depression based on Beck depression test (BECK Total score<29) 2- Be treated with one of the second generation antipsychotic drugs. 3- If there is another diagnosis based on DSM-5, it will be excluded from the study.

Intervention groups
The intervention group was given one gram of L-carnitine daily for eight weeks. The control group was given one gram of placebo (starch) daily for eight weeks.

Main outcome variables
Reduction of positive and negative symptoms, as well as reduction of side effects caused by antipsychotic drugs and schizophrenia itself, which is seen as metabolic syndrome.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191218045795N6**
Registration date: **2023-01-16, 1401/10/26**
Registration timing: **prospective**

Last update: **2023-01-16, 1401/10/26**
Update count: **0**

Registration date
2023-01-16, 1401/10/26

Registrant information
Name
Narges Shams alizadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 87 3366 8821
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-01-21, 1401/11/01
Expected recruitment end date
2024-09-21, 1403/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of L-carnitin as an adjunctive therapy in treatment of negative and positive symptom in schizophrenia

Public title

The effect of L-carnitin as an adjunctive therapy in treatment of negative and positive symptom in schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not having severe major depression based on Beck Depression Test (BECK Total score<29 have received psychiatric drugs with a fixed dose during the last 3 months. be treated with one of the second generation antipsychotic drugs

Exclusion criteria:

Presence of another diagnosis based on DSM-5 Intellectual disability Received ECT in the past 2 months History of substance and drug use except nicotine and caffeine History of seizures

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks of 4 Patients are placed in two groups A and B by the assistant and using random block method. For this randomization, the cans that have been prepared in advance and the drugs in them are done by the pharmacist and based on the patients in the order provided by the statistical consultant. The patient and the outcome examiner are unaware of which of these two groups will receive the drug or the placebo. How to randomly assign: People are assigned to intervention and control groups using the method of forming random blocks of 4 as follows. AABB, ABAB, BBAA, BABA A: Intervention Group B: Control Group Up to 48 people will be randomized using the formation of random blocks of 4 and random selection from the sequence of these blocks. For the remaining two people, each of them will be assigned to one of the intervention and control groups using the lottery method.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is done in a double blind way. The patients receiving the drug and the doctors who evaluate the outcomes are not aware of the random assignment of the subjects to the groups and the type of drug/placebo received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code

6617978743

Approval date

2022-09-21, 1401/06/30

Ethics committee reference number

IR.MUK.REC.1401.207

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

The score of positive and negative symptoms in the PANSS test

Timepoint

The beginning of the study, the end of the fourth week, the end of the eighth week

Method of measurement

Clinical interview based on PANSS

Secondary outcomes

1

Description

Metabolic syndrome

Timepoint
The beginning and end of the study
Method of measurement
Measurement of height and weight, blood pressure and waist circumference through clinical examination and measurement of triglycerides and cholesterol through paraclinics.

Intervention groups

1

Description
Intervention group: The drug used is l-carnitine 1000 mg, which is given to the intervention group daily for eight weeks, which is completely similar to the placebo drug in terms of weight and appearance.
Category
Treatment - Drugs

2

Description
Control group: The control group was given 1000 mg of placebo, which is mainly made of starch, flour, and coloring matter, and is completely similar to the main drug, L-carnitine, daily for eight weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Quds Hospital
Full name of responsible person
Narges Shamsalizadeh
Street address
Ẹntezam Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Afshin Maleki
Street address
Pasdaran Blvd
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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
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Narges Shamsalizadeh
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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/document
All personal data of participants can be shared after de-identification.
When the data will become available and for how long
The access period will start 6 months after the results are published.
To whom data/document is available
These data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
It will be determined after the completion of the study.
From where data/document is obtainable
To receive the data, the request is sent via email (n.shamsalizadeh@muk.ac.ir) to the address of the main executive.
What processes are involved for a request to access data/document
The applicant must clearly specify the purpose of receiving the information. The duration of sending the documents will be two months.
Comments