# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

**Phone**

+98 87 3366 8821

**Email address**

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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**
Entezam 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**
Psychiatrics
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## Person responsible for scientific inquiries

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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**