

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The effect of L-carnitine as an adjunct on cognitive abilities of patients with schizophrenia

#### Protocol summary

##### Study aim

the effect of L-carnitine as an auxiliary drug on the cognitive abilities of patients with schizophrenia

##### Design

This study is a randomized double-blind clinical trial on 60 patients with schizophrenia in phase 3, in which the quadruple random block method was used to separate the two groups.

##### Settings and conduct

60 schizophrenic patients were selected from among hospitalized patients and residents in care center in Sanandaj cities and were divided into placebo and intervention groups and were studied for 8 weeks. The intervention group was given 1 gram of L-carnitine daily. At the beginning of the study, at the end of the fourth and eighth week, all patients were evaluated with MMSE and WMS tests. The obtained data were subjected to statistical analysis

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Schizophrenia in the age range of 18 to 50 years, the stabilization of the clinical condition during the last 1 month using a fixed and standard treatment, the absence of any other medical or psychiatric disease affecting cognitive processes. Exit criteria: Coexistence of another psychiatric disorder, history of receiving ECT in the last 2 months, coexistence of substance abuse disorder or taking any other medication that affects the patient's cognitive abilities.

##### Intervention groups

Intervention group: The people who, in addition to the standard treatment of schizophrenia, receive 1000 mg of L-carnitine daily for 8 weeks. Control group: The people who receive placebo for 8 weeks in addition to the standard treatment of schizophrenia.

##### Main outcome variables

Main outcome: cognitive impairment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191218045795N8**

Registration date: **2023-02-28, 1401/12/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-02-28, 1401/12/09**

Update count: **0**

##### Registration date

2023-02-28, 1401/12/09

##### Registrant information

##### Name

Narges Shams alizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3366 8821

##### Email address

n.shamsalizadeh@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2024-08-22, 1403/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of L-carnitine as an adjunct on cognitive abilities of patients with schizophrenia

**Public title**

The effect of L-carnitine as an adjunct on cognitive abilities of patients with schizophrenia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Schizophrenia according to DSM-5 Absence of any other disease that negatively affects the patient's cognitive processes (dementia, hypothyroidism, intellectual disability, ID... based on clinical interview) receiving a fixed dose of drugs such as anticholinergics (bipyridine...) and benzodiazepines during the last 1 month Receiving regular standard treatment and having a stable and controlled clinical condition during the last 1 month

**Exclusion criteria:**

Coexistence of another psychiatric disorder according to DSM-5 Received ECT in the past 2 months Coexistence of substance abuse disorder and methadone according to DSM-5 Taking any medication that is prescribed due to cognitive problems or significantly affects the patient's cognitive processes

**Age**

From **18 years** old to **50 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**

The randomization method is performed as a four block randomization. In this way, the sequence of four blocks, AABB, are numbered as six sequences of four, for example, ABBA, from one to six. A table of random numbers is extracted from the Excel program, and according to those fifteen numbers, it is determined that thirty of them are A and thirty to B. The order of referral is involuntarily and randomly placed in group A or group B. Obviously, patients do not have the right to choose group A or group B.

**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 Highway, Kurdistan University of Medical Sciences

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Approval date**

2022-09-21, 1401/06/30

**Ethics committee reference number**

IR.MUK.REC.1401.193

**Health conditions studied****1****Description of health condition studied**

Schizophrenia

**ICD-10 code**

F20

**ICD-10 code description**

Schizophrenia

**Primary outcomes****1****Description**

Increasing the cognitive abilities of patients with schizophrenia following the administration of L-carnitine

**Timepoint**

The beginning, middle and end of the study

**Method of measurement**

Wechsler Memory Scale Questionnaire (WMS) and Brief Mental State Examination (MMSE)

**Secondary outcomes**

## 1

### Description

Changes in CRP serum levels

### Timepoint

The beginning and end of the study

### Method of measurement

Serum sample collection and quantitative measurement of CRP

## 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

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Quds Hospital

#### Full name of responsible person

Narges Shamsalizadeh

#### Street address

Entezam Blvd

#### City

Sanandaj

#### Province

Kurdistan

#### Postal code

6617113141

#### Phone

+98 87 3366 0025

#### Email

n.shamsalizadeh@muk.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Sanandaj University of Medical Sciences

#### Full name of responsible person

Afshin Maleki

#### Street address

Pasdarán Blvd

#### City

sanandaj

#### Province

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#### Postal code

6617978743

#### Phone

+98 87 3366 4957

#### Email

n.shamsalizadeh@muk.ac.ir

#### 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

#### Street address

Pasdarán Boulevard

#### City

sanandaj

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Sanandaj University of Medical Sciences  
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Narges Shamsalizadeh  
**Position**  
Associate Professor  
**Latest degree**  
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## Person responsible for updating data

### Contact

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**Postal code**

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### Phone

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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/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