Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Pasdaran Blvd
City
sanandaj
Province
Kurdistan
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
Pasdaran Boulevard
City
sanandaj
Province
Kurdistan
Postal code
6617978743
Phone
+98 87 3366 4957
Email
n.shamsalizadeh@muk.ac.ir

Person responsible for scientific 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
Pasdaran Blvd
City
sanandaj
Province
Kurdistan
Postal code
6617978743
Phone
+98 87 3366 4957
Email
n.shamsalizadeh@muk.ac.ir

Person responsible for updating data

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
Pasdaran Blvd
City
sanandaj
Province
Kurdistan
Postal code
6617978743
Phone
+98 87 3366 4957
Email
n.shamsalizadeh@muk.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
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