Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of L-carnnitine versus placebo on control of attention deficit-hyper activity disorder symptoms in Iranian children and adolescents, a double blind randomized clinical trial

Protocol summary

Summary

In this research, we intended to study the effect of L-carnitine a cognitive enhancer on symptom control of ADHD.This study is a double blind placebo controlled clinical trial. With block randomization method; 36 participants randomly divided in to case & control groups.Both groups will receive Methylphenidate as a standard treatment.Then drug or placebo will prescribed up to 50 mg/kg/day additionally. At the beginning of study, 3 & 6 weeks latter 3 questionnaire include Parent's conners questionaire, CGAS & Rachel & Klein Side effects Form will completed individually. Finally, the gathered data will analyzed statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090914598N1**
Registration date: **2013-09-20, 1392/06/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-20, 1392/06/29

Registrant information

Name

Fateme Sadat Noori

Name of organization / entity

Iran University Of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

tehran university of medical scienceVice chancellor for Research Tehran University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of L-carnnitine versus placebo on control of attention deficit-hyper activity disorder symptoms in Iranian children and adolescents, a double blind randomized clinical trial

Public title

Comparison the effect of L-carnitine versus placebo on control of Attention deficit-hyper activity disorder symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Age 6-16; Diagnosis of ADHD for the first time Exclusion criteria : IQ<70 ; Having other chronic medical illnesses; Be under other medications; Any serious or sever complication during study; Refusal of child or parent to continue the study

Age

From **6 years** old to **16 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for Research Tehran University of Medical Sciences
Street address
Vice chancellor for Research Tehran University of Medical Sciences, 7th Floor, Central Building of Tehran University of Medical Sciences, Corner of Qods St, Keshavarz Blvd,Tehran, Iran
City
Tehran
Postal code
Approval date
2013-08-17, 1392/05/26
Ethics committee reference number
20581

Health conditions studied

1

Description of health condition studied
Attention deficit-hyperactivity disorder
ICD-10 code
F90.0
ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
Attention, Impulsivity & Behavioral indecies
Timepoint
At the begining,3 weeks later & 6 weeks later
Method of measurement
Conner's parents questionaire

Secondary outcomes

1

Description
Child's general function
Timepoint
At the begining of study , 3 weeks later , 6 weeks later
Method of measurement
CGAS questionare

2

Description
Drug complication
Timepoint
3 weeks after begining of the study & 6 weeks later
Method of measurement
Rachell & klein Side effects Form

Intervention groups

1

Description
Intervention group will receive 50 mg/kg/day of L-carnitine syrup (product of shahr Darou company which contains 1g/10cc of drug) in divided dose,BID,morning and afternoon except taking Methylphenidate tablet.
Category
Treatment - Drugs

2

Description
Control group will receive 50 mg/kg/day of placebo (Sucrose solution in the same package and same dilution asL-carnitine syrup)BID,morning and afternoon except taking their Methylphenidate tablet.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Institute of Psychitry
Full name of responsible person
Dr Fateme Noori, Psychiatry Resident
Street address
Tehran Institute of Psychiatry, Shahid Mansouri St, Niayesh St, Sattarkhan St, Tehran, Iran
City
Tehran

2

Recruitment center

Name of recruitment center
Ali Asghar Children Hospital

Full name of responsible person
Dr Elham Shirazi, Associate Professor, Board of Subspeciality of Child and Adolescent Psychiatry

Street address
Ali Asghar Children Hospital, Zafar St, Modarres Ave, Tehran , Iran

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research Tehran University of Medical Sciences

Full name of responsible person
Dr Jalili

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Vice chancellor for Research Tehran University of Medical Sciences, 7th Floor, Central Building of Tehran University of Medical Sciences, Corner of Qods St, Keshavarz Blvd,Tehran, Iran

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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
Vice chancellor for Research Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran Institute of Psychiatry

Full name of responsible person
Dr Fateme Noori

Position
Psychiatry Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Dr Elham Shirazi

Position
Associate Professor, Board of Subspeciality of Child and Adolescent Psychiatry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty