

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

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

Protocol summary

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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 be prescribed up to 50 mg/kg/day additionally. At the beginning of study, 3 & 6 weeks later 3 questionnaires include Parent's Conners questionnaire, CGAS & Rachel & Klein Side effects Form will be completed individually. Finally, the gathered data will be analyzed statistically.

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Vice 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

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

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Phone

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Email address

Scientific title

Comparison the effect of L-carnitine 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 severe 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 questionnaire

Secondary outcomes

1

Description

Child's general function

Timepoint

At the begining of study , 3 weeks later , 6 weeks later

Method of measurement

CGAS questionnaire

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 Psychiatry

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

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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
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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

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Associate Professor, Board of Subspeciality of Child
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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