Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Ginkgo biloba in the treatment of ADHD in child and adolescent: a randomized clinical trial

Protocol summary

Summary

The aim of the present study is to evaluate the efficacy of Ginkgo Biloba on ADHD in children and adolescents through a double-blind, randomized, controlled trial. 40 outpatients, including 6-17 years old who clearly meet the DSM-IV-TR diagnostic criteria for ADHD(based on duiagnosis of a child psychiatrist) will be randomly assigned to receive Ginkgo biloba tablets (80mg/day) or methylphenidate (20 mg/day for those who are <30 Kg and 30 mg/day for those who are >30 Kg) for 6 weeks. The primary outcome measure is the Teacher and Parent ADHD Rating Scale- IV. Patients will be assessed by a child psychiatrist at baseline, 21 and 42 days after the medication started.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711151556N6**
Registration date: **2009-03-13, 1387/12/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-03-13, 1387/12/23

Registrant information

Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2007-04-20, 1386/01/31

Expected recruitment end date

2009-04-20, 1388/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ginkgo biloba in the treatment of ADHD in child and adolescent: a randomized clinical trial

Public title

Ginkgo biloba in the treatment of ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis of ADHD based on DSMIV age between 6-17 Exclusion Criteria: receiving of any psychotropics drugs during past two weeks, presence of any psychiatric disorders or mental retardation (I.Q. <70) except for ODD, History of Allergy to Ginkgo, presence of any medical problem including cardiovascular dieseases, presence of uncontrolled seizures

Age

From **6 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Keshavarz Blvd

City
Tehran

Postal code

Approval date
2007-04-20, 1386/01/31

Ethics committee reference number
5404

Health conditions studied

1

Description of health condition studied
Disturbance of activity and attention

ICD-10 code
F90.0

ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
Severity of ADHD

Timepoint
Week 0 (before treatment) and Weeks 3 and 6 after treatment

Method of measurement
Teacher and Parent ADHD Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Tablet Ginkgo Biloba 80 mg/day as intervention group for 6 weeks

Category
Treatment - Drugs

2

Description
Tablet Ritalin 20-30 mg/kg/day for 6 weeks as control group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh Hospital

Full name of responsible person
Prof. Mohammad Reza Mohhamadi

Street address
Roozbeh Hospital

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Akbar Foutouhi

Street address
Keshavarz Blvd

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Tehran

Grant name

Grant code / Reference number
5404

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
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Web page address

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