

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of Ginko biloba on attention deficit hyperactivity disorder (ADHD) symptoms in children aged 5 to 15 years

Protocol summary

Study aim

The aim of the study is to determine the effect of ginko biloba on the symptoms of attention deficit hyperactivity disorder including sleep quality, nutrition quality, growth rate and academic performance.

Design

A randomized clinical trial with a control group and a parallel group, a single blind phase 3 will be conducted on 30 patients with ADHD in two groups of 15 people. For randomization, the rand function of Excel software will be used.

Settings and conduct

study will be conducted in the Besat Hospital in Hamadan on children aged 5 to 15 with ADHD disorder. patients will be randomly assigned to intervention and control groups Before the intervention, both groups will be evaluated with Connors questionnaire in terms of symptoms of ADHD. Both groups will receive treatment and usual care for one month, the intervention group will receive 3 gr ginko biloba drugs orally in addition to the usual treatment and care. At the end of one 1month, both groups will be checked again for symptoms of ADHD with Connors questionnaire, person who evaluate patients at end of study will be blind of the groups (single blind).

Participants/Inclusion and exclusion criteria

The participants are 5-15 year old patients with attention deficit hyperactivity disorder. Conditions for not entering the study include patients with neurological or organic disorders and patients on a special diet

Intervention groups

The first group of patients with attention deficit hyperactivity disorder will receive 3 grams of ginko biloba medicine daily for one month at the same time as usual treatments. The second group of patients with ADHD will receive only the usual treatments, without ginko biloba medicine for one month.

Main outcome variables

The main outcome of the study is the changes in sleep

quality, nutrition quality, growth rate, academic performance and cognitive status.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N31**

Registration date: **2023-10-08, 1402/07/16**

Registration timing: **prospective**

Last update: **2023-10-08, 1402/07/16**

Update count: **0**

Registration date

2023-10-08, 1402/07/16

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of Ginkgo biloba on attention deficit hyperactivity disorder (ADHD) symptoms in children aged 5 to 15 years

Public title
Investigating the effect of Ginkgo biloba on attention deficit hyperactivity disorder symptoms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 5 to 15 years Normal IQ
Exclusion criteria:
patients with neurological or organic disorder Patients on a special diet

Age
From **5 years** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
We made 30 cards and write letter I on 15 for Intervention and on the other 15 letter C for the Control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter (I or C) patients will be assigned to Intervention or Control groups

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be conducted as single blind; In this way, the person who evaluating the outcome of the treatment will be blind about the treatment regimen

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Science

Street address

shahid fahmideh avenue

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6517789971

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR.UMSHA.REC.1402.248

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

The outcome of the study includes changes in symptoms of ADHD including sleep quality, nutrition quality, growth rate, academic performance, cognitive status.

Timepoint

Before treatment and one month after treatment

Method of measurement

Variables with the 26-question questionnaire of Connors, which contains questions about sleep quality, nutrition quality, growth rate, academic performance, and cognitive status.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In addition to the usual treatment and care, this group will receive 3 grams of ginkgo biloba medicine daily for one month.

Category

Treatment - Drugs

2

Description

Control group: The control group will only receive usual

care without receiving Ginkgo biloba medicine.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Afshin Fayazi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data can be shared except for authors names

When the data will become available and for how long

From March 2021

To whom data/document is available

Clinical professionals and Researchers in all fields

Under which criteria data/document could be used

To improve patients treatment and develop research and science

From where data/document is obtainable

Correspond to the email address of the scientific responsible for the study

What processes are involved for a request to access data/document

Send and receive email

Comments