

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation and comparison of plasma level of brain-derived neurotrophic factor before and after treatment with methylphenidate in children and adolescent with ADHD.

Protocol summary

Summary

The aim of this study is comparison of plasma level of brain-derived neurotrophic factor before and after treatment with methylphenidate in children and adolescent with ADHD. This is a before-after study without placebo. Samples consist of 30 children and adolescents suffering from ADHD who referring to the SHAFA hospital in Rasht. Sampling is based on DSM-IV oriented clinical interview and hemi-structured inventory of K-SADS. Inclusion criteria: age below 18, absence of any other axis I diagnosis, absence of any neurological disorder and use of psychotropic drug within the last month, IQ>70. Exclusion criteria: drug discontinue due to side effects, augmentation of any other psychotropic medication, occurring of any major neurological and psychiatric disorder, acute and febrile disease within current 2weeks. Plasma level of BDNF will be measured according to the kit instructions. After 4 weeks dose adjustment, patients will undergo treatment with methylphenidate more 6 weeks. Ultimately symptom severity and plasma Level of BDNF will be measured again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108067237N1**
Registration date: **2011-08-10, 1390/05/19**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-08-10, 1390/05/19

Registrant information

Name

Maryam Kousha

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 13 1666 1163

Email address

m-kousha@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research- Guilan University of Medical Sciences- Iran

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of plasma level of brain-derived neurotrophic factor before and after treatment with methylphenidate in children and adolescent with ADHD.

Public title

Evaluation of methylphenidate effect on brain growth factor.

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: age below 18; absence of any other axis I diagnosis; absence of any neurological disorder; use of psychotropic drug within the last month; IQ>70. Exclusion criteria: drug discontinuation due to side effects (tics, hallucinations, depressed mood, OCD, ...); augmentation of any other psychotropic medication; occurrence of any major neurological and psychiatric disorder (eg, depression, bipolar, psychotic disorders); acute and febrile disease within current 2 weeks.

Age

From **3 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

Before-After study

Secondary IDs

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Guilan University of Medical Sciences

Street address

Namjoo Street, Rasht

City

Rasht

Postal code

65385-41446

Approval date

2011-07-20, 1390/04/29

Ethics committee reference number

1900189601

Health conditions studied**1****Description of health condition studied**

ADHD

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes**1****Description**

BDNF (Brain-derived neurotrophic factor) plasma level

Timepoint

Before treatment, 10 weeks after treatment

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups**1****Description**

6 weeks treatment with effective dosage of methylphenidate

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shafa hospital

Full name of responsible person

Dr Maryam Kousha

Street address

Shafa hospital, Heshmat square, Rasht

City

Rasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Abdorrasool Sobhani

Street address

Namjoo street- Rasht

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Guilan 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*

Assistant professor

Other areas of specialty/work**Street address**

Shafa hospital, Heshmat square, Rasht

City

Rasht

Postal code**Phone**

+98 13 1666 6268

Fax**Email**

m-kousha@gums.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Maryam Kousha

Position

Assistant professor of psychiatry

Other areas of specialty/work**Street address**

Shafa hospital, Heshmat square, rasht

City

Rasht

Postal code**Phone**

+98 13 1666 6268

Fax**Email**

m-kousha@gums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Maryam Kousha

Position**Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Dr Maryam Kousha

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****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*