Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of methylphenidate’s effect on motor skills disorder in children with ADHD and developmental coordination disorder referred to Shafa hospital, Rasht 1390

Protocol summary

Summary

This research has two parts. In the first part, a child and adolescent psychiatrist does clinical interview and K-SAD's semi structure interview (timetable Cady for emotional disorders and schizophrenia school aged children). The patients with combined ADHD and DCD are enrolled. After filling demographic questionnaire and taking drug history, we perform physical examination and complete ADHD symptoms checklist. Then we try to estimate effective methylphenidate (MPH) dosage. This part lasts 4 weeks. Through a block randomization, each child receives 0.5, 0.75, or 1 mg/kg of MPh, or placebo each week and his/ her mother fills ADHD symptoms checklist. After one week washout period, we perform second part of the research. The patients are assigned into groups A or B. Each group receives MPH/ placebo or placebo/ MPH for one week. We perform BOT-2 test before intervention and at the end of the first and second weeks (3 times). The total duration of this research (including two parts) is 7 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107071483N2**
Registration date: **2011-07-13, 1390/04/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-07-13, 1390/04/22

Registrant information

Name

Mir Mohammad Jalali

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of methylphenidate’s effect on motor skills disorder in children with ADHD and developmental coordination disorder referred to Shafa hospital, Rasht 1390

Public title

Methylphenidate effect on fine motor skills of children with attention deficit/hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 6-11 years old, IQ score more than 70 on Raven's intelligence test, No associated psychiatric

disorders (pervasive developmental disorders, anxiety, conduct, mood disorders and schizophrenia), recent disease of ADHD-C or drug therapy less than 3 months prior to the study, No medical diseases (neurologic problems, seizures, cerebral palsy, sensory deficits including vision and hearing) Exclusion criteria: occurrence of side effects, poor compliance / irregular drug consumption

Age
From **6 years** old to **11 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

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
41446-65385

Approval date
2011-07-05, 1390/04/14

Ethics committee reference number
190015212

Health conditions studied

1

Description of health condition studied
developmental coordination disorder

ICD-10 code
F82

ICD-10 code description
Specific developmental disorder of motor function

Primary outcomes

1

Description
BOT 2 score

Timepoint
before intervention, the end of first and second week

Method of measurement
BOT 2 test

Secondary outcomes

1

Description
measurement of effective dosage of methylphenidate

Timepoint
before intervention and the end of 1, 2, 3 and 4 week

Method of measurement
ADHD symptoms checklist

Intervention groups

1

Description
methylphenidate therapy for one week

Category
Treatment - Drugs

2

Description
placebo for one week

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa hospital

Full name of responsible person
Dr Robabeh Soleimani Talemi

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

Person responsible for general inquiries

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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