Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Tipeptidine as adjuvant therapy in children with ADHD: A double blind and randomised trial

Protocol summary

Study aim
The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of tipetidine would improve psychopathology in subjects with ADHD treated with Ritaline

Design
randomized, double-blind, placebo controlled study

Settings and conduct
The study will be conducted among patients attending Roozbeh Hospital-Tehran

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of ADHD based on DSM-5; age between 6-17 years old. Exclusion criteria: Intellectual disability; presence of any psychiatric disorders except for ODD; receiving any neuroleptic during the last 6 months, history of allergy to tipetidine or Ritaline; presence of any medical problem including cardiovascular diseases; presence of uncontrolled seizures; systolic blood pressure more than 120 mm Hg; resting pulse rate less than 60/minute or more than 115/minute

Intervention groups
Ritaline 10 to 30 mg per day and placebo as control group for 8 weeks Ritaline10 to 30 mg per day and tipetidine 30 mg per day as inervention group for 8 weeks

Main outcome variables
Severity of ADHD

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N108**
Registration date: **2018-04-06, 1397/01/17**
Registration timing: **prospective**
Last update: **2018-04-06, 1397/01/17**
Update count: **0**

Registration date
2018-04-06, 1397/01/17

Registrant information

Name
Shahin Akhondzadeh

Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 5541 2222

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-19, 1397/01/30

Expected recruitment end date
2020-04-18, 1399/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Tipeptidine as adjuvant therapy in children with ADHD: A double blind and randomised trial

Public title
Tipeptidine as adjuvant therapy in children with ADHD

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of ADHD based on DSM-5 Age between 6-17 years old
Exclusion criteria:
Intellectual disability Presence of any psychiatric disorders except for ODD Receiving any neuroleptic during the last 6 months Weight less than 13.5 kg History of allergy to Tipeptidine or Ritaline Presence of any neurologic disease and any condition requiring surgery Uncontrolled seizures Systolic blood pressure more than 125 mm Hg; resting pulse rate less than 60/minute or more than 115/minute Severe medical disease Receiving any medication or supplement for treatment ADHD

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Random blocks (each block has four cases)

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, clinicians and outcome evaluators will be blind regarding grouping

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Keshavarz Blv

City
tehran

Province
Tehran

Postal code
1417653761

Approval date
2019-03-03, 1397/12/12

Ethics committee reference number
IR.TUMS.VCR.REC.1396.4676

Health conditions studied

1

Description of health condition studied
Disturbance of activity and attention

ICD-10 code
F90.2

ICD-10 code description
Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description
Severity of ADHD

Timepoint
Week 0 (before treatment) and Weeks 4 and 8 after treatment

Method of measurement
Teacher and Parent ADHD Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Ritaline 10 to 30 mg per day and placebo as control group for 8 weeks

Category
Placebo

2

Description
Intervention group: Ritaline 10 to 30 mg per day and tipetidine 30 mg per day as intervention group for 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh Hospital

Full name of responsible person
Prof. Shahin Akhondzadeh

Street address

Roozbeh Hospital, South Kargar Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
Position
Prof. of Clinical Psychopharmacology
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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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
Yes - There is 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 will be distributed through final report
When the data will become available and for how long
from 2021 to 2026
To whom data/document is available
academic researchers
Under which criteria data/document could be used
by E mail
From where data/document is obtainable
prof Shahin Akhondzadeh
What processes are involved for a request to access data/document
s.akhond@sina.tums.ac.ir
Comments