Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Comparison Atomoxetine Versus Ritalin in pediatric outpatients with attention deficit hyperactivity disorder

Protocol summary

Study aim
treatment with efficient drugs for the disorder

Design
patient doesn’t know about wich drugs he or she used but because the forms and shapes of drugs are different maybe they would understand the drug differences.Researcher knows which drugs are used for patients.Patients are devided into 2 groups randomly

Settings and conduct
Yahyanejad hospital clinic, Babol University of Medical Sciences. ADHD-RS questionnaire or attention deficit hyper activity disorder rating scale is a questionnaire which has 18 questions used for a measurement of ADHD recovery in different studies.Time for filling out the questionnaire is about 5 minutes.Psychologist asks questions from children and then completes the form of questionnaire and rates the answers.

Participants/Inclusion and exclusion criteria
pediatric outpatients with attention deficit hyperactivity disorder. Inclusion criteria: ADHD disorder(all types)was diagnosed on the base of attention deficit-hyperactivity DSM-V system criteria,pediatric; patients with ADHD diagnosis who were maltreated,patient don’t suffer from hepatic, cardiac,renal or chronic diseases which have required special care;patients haven’t used MAOI drugs during recent 15 days. Exclusion criteria: eating disorders; substance use disorders; psychiatric disorders such as tic, mental ,pervasive developmental disorders,personal or familial history of Tourette syndrome; seizure; history of Hyperthyroidism,glaucoma; using of drugs that are contraindicated with Ritalin or Atomoxetin; patients with history of no response to prior medications of ADHD; occurrence of menstruation in girls.

Intervention groups
Group 1: 30 patients receive Ritalin (Novarits company, Riralin). Group 2: 30 patients receive Atomoxetin(Abidi company, Stramox).

Main outcome variables
ADHD-RS questionnaire

General information

Reason for update

Acronym
ADHD

IRCT registration information
IRCT registration number: **IRCT20170606034348N1**
Registration date: **2018-03-14, 1396/12/23**
Registration timing: **retrospective**

Last update: **2018-03-14, 1396/12/23**
Update count: **0**

Registration date
2018-03-14, 1396/12/23

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 121 3171

Email address
a.hamidia@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-09-21, 1395/06/31

Expected recruitment end date
2017-09-22, 1396/06/31

Actual recruitment start date
2016-09-21, 1395/06/31

Actual recruitment end date
2017-09-22, 1396/06/31

Trial completion date

empty

Scientific title
Comparison Atomoxetine Versus Ritalin in pediatric outpatients with attention deficit hyperactivity disorder

Public title
Effect of Atomoxetin Versus Ritalin in pediatric outpatients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ADHD disorder (all types) was diagnosed on the base of attention deficit-hyperactivity DSM-V system criteria. patients with ADHD diagnosis who were maltreated cardiac, renal or chronic diseases which have required special care. patients haven't used MAOI drugs during recent 15 days

Exclusion criteria:
Exclusion criteria: eating disorders; substance use disorders; psychiatric disorders such as tic, mental, pervasive developmental disorders,personal or familial history of Turette syndrome; seizure; history of Hyperthyroidism, glaucoma; using of drugs that are contraindicated with Ritalin or tomoxetin; patients with history of no response to prior medications of ADHD; occurrence of menstruation in girls.

Age
From **6 years** old to **14 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
randomly

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق پزشکی علوم پزشکی بابل

Street address
Babol University of Medical Sciences,Ganjafrooz street

City
Babol

Province
Mazandaran

Postal code
45745-47176

Approval date
2016-02-28, 1394/12/09

Ethics committee reference number
MUBABOL.REC.1394.322

Health conditions studied

1

Description of health condition studied
attention deficit-hyperactivity disorder

ICD-10 code
F90.9

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

Primary outcomes

1

Description
ADHD-RS questionnaire

Timepoint
at the end of 4th and 8th weeks after starting treatment

Method of measurement
ADHD-RS questionnaire or attention deficit hyper activity disorder rating scale is a questionnaire which has 18 questions used for a measurement of ADHD recovery in different studies.Time for filling out the questionnaire is about 5 minutes.Psychologist asks questions from children and then completes the form of questionnaire and rates the answers.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 patients receive Ritalin (Novarits company, Riralin)

Category
Treatment - Drugs

2

Description
Intervention group: 30 patients receive Atomoxetin (Abidi company, Stramox)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yahyanejad hospital clinic
Full name of responsible person
Anjela Hamidia
Street address
Yahyanejad Hospiyal,Moddares street,Mostafa khomeinei street, Babol,Mazandaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol 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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Anjela Hamidia
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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