Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of methylphenidate and atomoxetine in the treatment of attention deficit hyperactivity disorder in adult patients

Protocol summary

Study aim
The comparison of effectiveness and adverse effects of Methylphenidate and Atomoxetine in adult ADHD

Design
Clinical trial phase 3, blocked randomized, with sample size of 36 patients, two intervention groups receiving methylphenidate or atomoxetine

Settings and conduct
Patients with attention deficit hyperactivity disorder are chosen at adult clinic of Roozbeh hospital or psychiatrist's private office. Each patient will randomly receive one of the drugs of methylphenidate or atomoxetin with suitable dosage. Severity of inattentive and hyperactivity symptoms will be analyzed through Conners questionnaire each two weeks for period of two months. Effectiveness and side effects of the drugs is also analyzed through Hamilton depression and anxiety questionnaire, general assessment of functioning scale and drugs adverse effects questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with attention deficit hyperactivity disorder; 19-50 years old age Exclusion criteria: History of any other disorders

Intervention groups
Intervention group 1: Patients who receive methylphenidate 10 milligram tablets (Ritalin) manufactured by Novartis pharmaceutical industry in Switzerland three times daily for two months..
Intervention group 2: Patients who receive atomoxetine capsules (Stramox) manufactured by Tadbire kalaye jam pharmaceutical industry n Iran once daily for two months. For both groups the effectiveness and drugs adverse effects is analyzed with suitable questionnaires.

Main outcome variables
The score of attention deficit hyperactivity disorder in Conners questionnaire, the score of general assessment of functioning index, the score of Hamilton anxiety and depression questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110802007202N15**
Registration date: **2018-11-08, 1397/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-08, 1397/08/17**
Update count: **0**

Registration date
2018-11-08, 1397/08/17

Registrant information

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Padideh Ghaeli

Name of organization / entity
Tehran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-01, 1397/05/10

Expected recruitment end date
2019-01-05, 1397/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of methylphenidate and atomoxetine in the treatment of attention deficit hyperactivity disorder in adult patients

Public title
Methylphenidate and atomoxetine in attention deficit hyperactivity disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Attention Deficit Hyperactivity Disorder Age between 19-50 years Signing consent form

Exclusion criteria:
Patients with a history of any systemic disorder such as cardiovascular diseases Patients with a history of bipolar disorder, major depressive disorder, psychosis, substance abuse, pervasive developmental disorder and intellectual disability Using psychotropic drugs within one month prior to the initiation of the study

Age
From **19 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
For designating patients in 2 groups, blocked randomization method is used. The unit of randomization is individual-based and due to the sample size of 36, eighteen of 2-unit blocks are generated. In order to determine the random sequence, “Coin Flip” method is used for assigning the first patient in each block. The first patient is placed in group A if the “head” side is seen as the result of the coin flip and if otherwise, the “tail” is seen, the patient is placed in group B. To generate the random sequence, this process is repeated for next set of blocks until the final patient is designated to the assigned group. To conceal the randomized allocation, the sequentially numbered, opaque sealed envelopes (SNOSE method) is used. 36 opaque numbered envelopes are provided, then each of the sequences is recorded on a card and inserted in an envelope. Finally, the envelopes are placed in a box. At the time of participation of each patient in the trial, the first envelope is opened and the patient 's group is revealed. The random allocation process is done by the hospital pharmacist who does not participate in the study.

Blinding (investigator's opinion)
Single blinded

Blinding description
It is impossible to blind the physician, patient and data coordinator who is the researcher in this study due to the kind of disease and the medicines. This study is single blinded and the analyzer is unaware of the kind of the medicines given to the patients. The data gathered during the study of patients by the researcher is then unknowingly given to the analyzer and statistics expert.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Pharmaceutical Sciences Research Center of Tehran University of Medical Sciences

Street address
Faculty of Pharmacy, Tehran University of Medical Sciences, 16th Azar Street., Tehran

City
Tehran

Province
Tehran

Postal code
14155-6451

Approval date
2017-12-02, 1396/09/11

Ethics committee reference number
IR.TUMS.PSRC.REC.1396.4138

Health conditions studied

1

Description of health condition studied
Attention deficit hyperactivity disorder in adults

ICD-10 code
F90.9

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

Primary outcomes

1

Description
Score of inattentive and hyperactive symptoms in Conners Adult ADHD Rating Scale - self report questionnaire

Timepoint
Before intervention and 2, 4, 6 and 8 weeks after the intervention

Method of measurement
Self report Conners Adult ADHD Rating Scale

questionnaire

Secondary outcomes

1

Description
The score of Hamilton Depression questionnaire
Timepoint
Before intervention and 8 weeks after the intervention
Method of measurement
Hamilton depression questionnaire

2

Description
The score of Hamilton Anxiety questionnaire
Timepoint
Before intervention and 8 weeks after the intervention
Method of measurement
Hamilton Anxiety questionnaire

3

Description
The score of general assessment of functioning scale
Timepoint
Before intervention and 8 weeks after the intervention
Method of measurement
General assessment of functioning scale

Intervention groups

1

Description
Intervention group 1: Pharmacotherapy with methylphenidate 10 milligram immediate release tablets (Ritalin) manufactured by Novartis pharmaceutical industry in Switzerland. The medicine's dosage is determined by psychotherapist but routinely it starts with 5 milligrams three times daily for one week and then it is increased to 10 milligrams three times daily. (Based on the medicine's effectiveness and adverse effects, the dose can be increased up to 1.2 milligrams per body weight kilograms per day.)
Category
Treatment - Drugs

2

Description
Intervention group 2: Pharmacotherapy with atomoxetine capsules (Stramox) manufactured by Tadbire kalaye jam pharmaceutical industry in Iran. The medicine's dosage is determined by psychotherapist but routinely it starts with 10 milligrams daily for the first week and then the dose is increased to 20 milligrams for the next two weeks and finally to 40 milligrams per day. (Based on the medicine's effectiveness and adverse effects, the dose can be increased up to 1.2 milligrams per body weight kilograms per day.)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Adult's clinic of Roozbeh hospital
Full name of responsible person
Dr.Valentin Artonian
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Email
Hosp_roozbeh@tums.ac.ir
Web page address
http://roozbehhospital.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraeian
Street address
6th floor, Central Organization of the University., Ghods St., Keshavarz Blvd
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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
Parya Tajmehrabi Namini
Position
Pharm.D student
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available