

# 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 atomoxetine 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 in 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

##### Name

Padideh Ghaeli

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

pghaeli@sina.tums.ac.ir

##### 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

##### Street address

Roozbeh Hospital, South Kargar St

##### City

Tehran

##### Province

Tehran

##### Postal code

1333715914

##### Phone

+98 21 5541 9151

##### 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

##### City

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##### Province

Tehran

##### Postal code

1417614411

##### Phone

+98 21 8163 3698

##### Email

rmo@tums.ac.ir

#### 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

1417614411

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

Tehran University of Medical Sciences

**Full name of responsible person**

Parya Tajmehrabani Namini

**Position**

Pharm.D student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for updating data****Contact****Name of organization / entity**

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Pharm.D student

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

Tehran University of Medical Sciences

**Full name of responsible person**

Padideh Ghaeli

**Position**

Associate professor in clinical pharmacy group of  
Tehran University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy, Tehran University of Medical  
Sciences, 16 Azar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code****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