

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Atomoxetine on stuttering of children in 4-12 years old referring to neurological clinic in Ardabil

Protocol summary

Study aim

Applying Atomoxetine for treatment of stuttering

Design

Clinical trials with control group, with parallel groups, double blind, non-randomized

Settings and conduct

A group of patients with stuttering children aged 4 to 12 years old, They are randomly divided into two groups. One group, in addition to undergoing speech therapy, is treated with a daily dose of 0.5 kg / mg The car will also be placed, and the other will only be treated with speech therapies. Stuttering rate in both groups before and after 3 months Treatment is based on the severity stuttering tool (SSI4), and the results will be compared. The other step is for That the effect of the drug is proven apart from the effectiveness of speech therapies, the two groups will change together. So that the group treated with the drug this time For 3 months only speech therapy will be received, and the group who did not receive the medication will receive both medication and speech therapies. Then again the results Will be investigated and compared. In the case of efficacy, the drug will be evaluated in a blind, double-blind, and placebo-controlled trial.

Participants/Inclusion and exclusion criteria

All 4-12 year stuttering patients referred to Ardabil neurology clinic during a 2 month period

Intervention groups

Prescribing atomoxetine with a dose of 0.05 mg/kg daily for 3 months

Main outcome variables

severity of stuttering; SSI4 scoring

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044247N1**

Registration date: **2019-08-13, 1398/05/22**

Registration timing: **prospective**

Last update: **2019-08-13, 1398/05/22**

Update count: **0**

Registration date

2019-08-13, 1398/05/22

Registrant information

Name

Akram Motamedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3325 2251

Email address

amot314@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Atomoxetine on stuttering of children in 4-12 years old referring to neurological clinic in Ardabil

Public title

Evaluation of Atomoxetine on stuttering of children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All 4 to 12 year-old patients with stuttering.

Exclusion criteria:
Patients aged 12 to 4 years with stuttering with brain or evolutionary problems. Patients aged 4 to 12 years with stuttering do not go on a three-month follow-up to continue treatment. Patients aged 4 to 12 years with stutter, who are treated with a drug other than atomextin.

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients referred to the neurology clinic will be arranged in the order of referral in the intervention group with the main drug and placebo group. The medication will be prescribed for a period of three months. At the end of the three months, the group who received the original drug will be given a placebo and the placebo group will receive the original drug (atomoxetine).

Placebo
Used

Assignment
Parallel

Other design features
In this project intervention group and placebo group will change to eradicate influence of speech therapy on results.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics Committee of Ardabil Medical Science University, National Ethics Committee for Biomed

Street address

Boali pediatrics hospital, Varzesh square, Ardabil.

City

Ardabil

Province

Ardabil

Postal code
5613643197

Approval date
2019-06-12, 1398/03/22

Ethics committee reference number
IR.ARUMS.REC.1398.101

Health conditions studied

1

Description of health condition studied

Stuttering

ICD-10 code

F98.5

ICD-10 code description

stuttering

Primary outcomes

1

Description

stuttering severity

Timepoint

Beginning of intervention and end of the 3 month period

Method of measurement

Severity Measurement Tool SSI4

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Including 50 patients who will be referred to the Pediatric Neurology Clinic for 2 months and randomly assigned to the Atomoxetine treatment group. This group will take the drug for 3 months. At the beginning and end of this three-month period, the stuttering severity assessment form will be completed. During the intervention, standard treatment, which is speech therapy, will be provided for all of these patients.

Category

Treatment - Drugs

2

Description

Control group: Including 50 patients who will be referred to the pediatric neurology clinic within 2 months and will be randomly assigned to a placebo treatment group. This group will use placebo for 3 months. At the beginning and end of this three-month period, the stuttering severity assessment form will be completed. During the intervention, standard treatment, which is speech therapy, will be provided for all of these patients.

Category

Placebo

3

Description

Intervention group: This group includes the same 50 patients in control group 1 who will receive atomoxetine for another 3-month period. Standard stuttering (speech therapy) will also continue for this group.

Category

Treatment - Drugs

4

Description

Control group: This group includes the same 50 patients in intervention group 1 who will receive placebo for another 3-month period. Standard stuttering (speech therapy) will also continue for this group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatrics Neurologic clinic

Full name of responsible person

Farzad Ahmadabadi

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Boali Pediatric Hospital, Varzesh square, Ardabil

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Farzadpt@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Shahab Bohlooli

Street address

Ardabil University of Medical Sciences, Ardabil, Iran

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Province

Ardabil

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Phone

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Email

s.bohloli@pharmacy.arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Akram Motamedi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of the study will include the efficacy of Atomoxetine on the severity of stuttering. The main characteristics of the patients, including their first name, will not be published. Other general specifications, including age and sex, and the extent to which they are communicated and their effect on stuttering, will be provided.

When the data will become available and for how long

Since the beginning of 1399

To whom data/document is available

Academic or non-academic researchers

Under which criteria data/document could be used

Using the results of the study with its source is allowed

From where data/document is obtainable

Ardabil University of Medical Sciences at
www.arums.ac.ir

What processes are involved for a request to access data/document

By accessing the site of Ardabil University of Medical Sciences, you can access the information of this research by selecting the library's digital library option.

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

Ardabil University of Medical Sciences

Full name of responsible person

Akram Motamedi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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