

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Randomized Clinical Trial, effects of combination treatment with Tizanidine and long-acting Stimulants in ADHD.

Protocol summary

Study aim

Study the effects of combination treatment of Tizanidine with long acting Stimulants in Attention Deficit Hyperactivity Disorder

Design

randomized clinical trial, parallel group, double blinded, randomized, phase 3 on 40 ADHD patients between age 9-18 years, Randomization carried out with an external site (randomizer.org)

Settings and conduct

This trial will be conducted during 3 phases (0, 1, 2 month) in resistant ADHD patients between age 9-18 that be visited in outpatient units or admission wards of department of child psychiatry of Isfahan University of Medical Sciences. All of participants, health care providers (that are involved in offering drug or placebo) and data collectors and assessors will be blinded with similarity in form and shape of drug and placebo and numerical codes for each participant instead of name in all time of study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinical diagnosis of ADHD according to Diagnostic and Statistical Manual of mental disorder-5 (DSM-5) criteria, completing the informed consent form by patient and parents, negative history of receiving any Antihypertensive drug or Alfa blocker or Beta blockers, negative history of allergic reaction to drug. Exclusion criteria: unwillingness of patient or family to continue the study and any new medical or mental conditions that effects treatment procedure.

Intervention groups

Intervention group will receive combination of Vyase and Tizanidine (drug A) and control group will receive Vyase and placebo (drug B)

Main outcome variables

In the beginning of study and in end of month 1 and 2, severity of ADHD will be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230619058530N2**

Registration date: **2023-10-14, 1402/07/22**

Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**

Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Mostafa Haghshenas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 8000

Email address

m.haghshenas@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-04-17, 1403/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized Clinical Trial, effects of combination treatment with Tizanidine and long-acting Stimulants in ADHD.

Public title

Effects of combination treatment with Tizanidine and long-acting Stimulants in ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of Attention Deficit Hyperactivity Disorder according to DSM-5 criteria completing the informed consent form by parent and patient negative history for any chronic medical diseases negative history for drug induced allergy negative history of receiving any Anti hypertensive, Alpha blockers or Beta blockers during recent three months before study Lack of history of any comorbid psychiatric disorder

Exclusion criteria:

Any unexpected physical or mental condition that effects on treatment regimen unwillingness of patients or parents to continue study procedure

Age

From **9 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

according to time sequence of visits, each sample will give specific code between 1-40 and then, by means of an online computer randomization tool(random.org),they will be randomized in intervention or placebo group with a simple randomization manner by a 1:1 ratio. For blinding, each participant would be shown as an numerical code until the end of study.

Blinding (investigator's opinion)

Double blinded

Blinding description

blinding procedure in both intervention and control groups will be done by similarity in shape of drug and placebo. blinding of principle investigator will be done by random placing of participants in both control and intervention groups and each participant will have a numerical code. health care providers offer the drug and placebo base on A and B codes to participants. with a similar process, that mentioned above, data collectors and outcome assessors will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the "Alzahra Research Centers

Street address

Hezar-Jerib street

City

esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-08-22, 1402/05/31

Ethics committee reference number

IR.ARI.MUI.REC.1402.135

Health conditions studied

1

Description of health condition studied

Attention-deficit hyperactivity disorders

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

ADHD severity

Timepoint

Before intervention and 1,2 months after intervention

Method of measurement

conners questioner

Secondary outcomes

1

Description

blood pressure

Timepoint

Before intervention and 1,2 months after intervention

Method of measurement

Standard mercury sphygmomanometer

Intervention groups

1

Description

Intervention group: tizanidine tablet (Tizanidine 4MG TAB, Hakim Pharmacy) with dose 1-4mg daily, divided doses orally for 2 month

Category

Treatment - Drugs

2

Description

Control group: placebo tablet(School of Pharmacy and Pharmaceutical SciencesSchool of Isfahan University of Medical Sciences) contains starch and calcium diphosphate ,orally and divided daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Majid Hosseinzadeh

Street address

Ebn e Sina street

City

esfahan

Province

Isfahan

Postal code

8148653141

Phone

+98 31 1445 5051

Email

Amin@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Hezar Jerib street

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

askari@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mostafa Haghshenas

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Hezar Jerib Street

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3222 2475

Email

haghshenas2005@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mostafa Haghshenas

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Hezar-Jerib street
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3222 2475
Email
haghshenas2005@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mostafa Haghshenas
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Hezar-Jerib street
City
Esfahan
Province

Isfahan
Postal code
8174673461
Phone
+98 31 3222 2475
Email
haghshenas2005@gmail.com

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