Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of efficacy of treatment with lisdexamphetamine (vyas) in comparison with extended release methylphenidate (sandoz) on improving the quality of life and executive function of adults with attention deficit hyperactivity disorder : an open-lable randomized clinical trial

Protocol summary

Study aim

comparing the therapeutic effects and side effects of treatment with lisdexamfetamine (Vyas®) versus sustained release methylphenidate (Sandoz) on improving the quality of life and executive function of adults with attention deficit hyperactivity disorder

Design

This study is an open label randomized clinical trial phase 2, 3 on 56 patients, which prospectively investigates and compares the therapeutic effects and side effects caused by treatment with lisdexamfetamine versus methylphenidate sustained release. Improving the quality of life and executive functioning of adults with ADHD. Patients are randomly divided into two treatment groups, lisdexamfetamine or methylphenidate, based on the unlimited randomization method.

Settings and conduct

Patients referred to Rozbeh hospital, who were diagnosed with DIVA-5 test and based on DSM-5 criteria, were randomly assigned with informed consent and based on unlimited randomization method, equally to two treatment groups.One of the two drugs is prescribed to the patient based on availability

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age more than 16 years Diagnosis of adult ADHD based on DSM-5 Diagnosis of adult ADHD based on DIVA-5 Exclusion criteria: Use of Alcohol and other substances History of Bipolar or psychotic disorders Other psychiatric disorders such as MDD or Autism spectrum disorder Pregnancy or Lactation hypersensitivity to drugs used in this study Neurologic disorders or severe Hepatic or Renal disease Dependency to drugs ex. Benzodiazepines MDMA and other substances History of not responding to stimulants Use of any other drug with effects on CNS

Intervention groups

Two intervention groups where adults with attention deficit hyperactivity disorder who are randomly treated with one of the two drugs are studied.

Main outcome variables

Improvement in the quality of life.Improvement in executive functioning

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056238N1**
Registration date: **2022-11-21, 1401/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-21, 1401/08/30**
Update count: **0**

Registration date

2022-11-21, 1401/08/30

Registrant information

Name

Azin Aivazziaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2223 4676

Email address

a-aziaei@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-10-30, 1401/08/08
Expected recruitment end date
2023-02-27, 1401/12/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of efficacy of treatment with lisdexamphetamine (vyas) in comparison with extended release methylphenidate (sandoz) on improving the quality of life and executive function of adults with attention deficit hyperactivity disorder : an open-lable randomized clinical trial

Public title
Comparison of lisdexamphetamine and and methylphenidate in adult ADHD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 16 years Diagnosis of adult attention deficit hyperactive disorder based on DSM-5 Diagnosis of adult attention deficit hyperactive disorder based on DIVA-5
Exclusion criteria:
Alcohol and other substance us History of Bipolar or psychotic disorders Other psychiatric disorders such as MDD or Autism spectrum disorder Pregnancy or Lactation hypersensitivity to drugs used in this study Neurologic disorders or severe Hepatic or Renal disease BMI less than 18 Dependency to drugs ex. Benzodiazepines MDMA and other substances History of not responding to stimulants Use of any other drug with effects on CNS
Age
From **16 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is based on simple randomization method. Foremost, it is agreed that odd numbers will be given to intervention group A (Dex amphetamine treatment) and even numbers will be given to intervention group B (Methylphenidate treatment). Then, according to the number of the studied sample, random numbers or relevant numbers are extracted from the table, each number is written on a card and placed in an envelope, the envelopes are sealed, and the patient's number is written on each envelope. The first patient who is enrolled in the study will be given the envelope number 1, patient number 2, envelope number 2 and so on, this will continue until the end of the study sampling. In order to maintain randomization, the person who prepares the envelopes is different from the main researcher who registers the patients and provides the envelopes to the patients.
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
Ethics committee of medical faculty of university of Tehran
Street address
Faculty of medicine , Tehran university of medical science , poursina Ave. qods Ave. enghelab Ave
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2022-08-13, 1401/05/22
Ethics committee reference number
IR.TUMS.MEDICINE.REC1401346

Health conditions studied

1

Description of health condition studied
ADULT ADHD
ICD-10 code
F90
ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
Primary outcome measure includes changes in scores of BDEFS and WHOQOL scores from the beginning to the

end of study.

Timepoint

before intervention then 2,4,8 weeks after intervention

Method of measurement

Questioner of Barkley deficits in executive functioning scale for adults , WHO Questioner of quality of life , Clinical global impression GCI Questioner.

Secondary outcomes

empty

Intervention groups

1

Description

The first group that receives Lisdexamfetamine (Vyas) for the treatment of ADHD, which will be continued for 8 weeks for each patient. The low dose of drug will start based on the interview and the patient's condition, and the dose will gradually increase according to the patient's symptoms and drug side effects. The optimal dose is 50 mg daily.

Category

Treatment - Drugs

2

Description

The second group that receives sustained release Methylphenidate (Sandoz) for the treatment of ADHD, which will be continued for 8 weeks for each patient. The low dose of drug will start based on the interview and the patient's condition, and the dose will gradually increase according to the patient's symptoms and drug side effects. The optimal dose is 54 mg daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Azin Aivazziaei

Street address

Roozbeh hospital south Karegar Ave.

City

Tehran

Province

Tehran

Postal code

133715914

Phone

+98 21 5541 9151

Email

hosp_roozbeh@tums.ac.ir

Web page address

https://roozbehhospital.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Vice-Chancellor of Research Affairs, Floor 6th, Tehran University of Medical Sciences central building, Qods St. Tehran University of Medical Sciences,Tehran,Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

vcr@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

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Azin Aivazziaei

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Roozbeh hospital south Karegar Ave.

City

Tehran

Province

Tehran
Postal code
133715914
Phone
+98 21 5541 9151
Email
a-aziaei@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Azin Aivazziaei
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Roozbeh hospital south Karegar Ave.
City
Tehran
Province
Tehran
Postal code
133715914
Phone
+98 21 5541 9151
Email
a-aziaei@razi.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Azin Aivazziaei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Roozbeh hospital south karegar Ave.
City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 5541 9151
Email
a-aziaei@razi.tums.ac.ir

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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The use in other scientific researches is unimpeded by observing the publication rules and mentioning the source
From where data/document is obtainable
Application by email to the clinical trial registrar
What processes are involved for a request to access data/document
After making sure that the data will be clearly used in other scientific researches with reference to the source, it will be delivered to the researcher
Comments