

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comprehensive evaluation of lisdexamfetamine dimesylate in treatment of binge eating disorder alone and in combination with topiramate in 18_55 year_old adults

Protocol summary

Study aim

Comprehensive evaluation of lisdexamfetamine dimesylate in treatment of binge eating disorder alone and in combination with topiramate

Design

Two arm parallel group randomized clinical trial with Permuted block randomization method and blinded outcome assessment comprehensive study of the two group is done before and after intervention

Settings and conduct

In the present randomized clinical trial study, 93 patients were selected by convenience sampling method and were allocated to two groups of 48 (lisdexamfetamine dimesylate alone) and 45 (lisdexamfetamine dimesylate with topiramate) using the permuted block randomization method. The diagnosis was made by the second author who is a well experienced psychiatrist through a systematic interview and filling up the Gormally questionnaire. Participant selected within who referred to medical clinics of the city Shiraz. The patients get treated for 12 weeks. Prior entering the study, the participants were given the necessary explanations regarding the research and informed consent was obtained from them. It should be noted, blinding is not done in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria : Participants aged 18-55 years old meeting the diagnostic criteria for BED according to DSM-5
Exclusion criteria : posing other major psychological disorders assessed by psychiatrists (depression ,anxiety,...) Posing physical disease (.thyroid function disease ,gastrointestinal or cardiovascular disease) known sensitivity to LDX or TPM.

Intervention groups

Lisdexamfetamine dimesylate alone group 1

Lisdexamfetamine dimesylate with topiramate group 2

Main outcome variables

binge eating score .BMI.weight .cholesterol.lipid profile.liver anzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230910059396N1**

Registration date: **2023-11-04, 1402/08/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-04, 1402/08/13**

Update count: **0**

Registration date

2023-11-04, 1402/08/13

Registrant information

Name

Farnoosh Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4223 3201

Email address

farmokhtarii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-16, 1402/06/25

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comprehensive evaluation of lisedexamfetamine dimesylate in treatment of binge eating disorder alone and in combination with topiramate in 18_55 year_old adults

Public title
evaluation of lisedexamfetamine dimesylate in treatment of binge eating disorder alone and in combination with topiramate in adults

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Participants aged 18-55 years old meeting the diagnostic criteria for BED according to DSM-5
Exclusion criteria:
Posing other major psychiatric disorders assessed by psychiatrists (anxiety, depression,...) Posing physical disease like cardiovascular diseases, thyroid disturbances or gastrointestinal diseases known sensitivity to LDX or TPM.

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present randomized clinical trial study, 93 patients were selected by convenience sampling method and were allocated to two groups of 48 (lisedexamfetamine dimesylate alone group A) and 45 (lisedexamfetamine dimesylate in combination with topiramate group B) using the permuted block randomization method. This is an individual randomization which is done using random allocation software, and a permutation block design was used, where the groups are coded as A, B. Block randomization method with blocks of four is one of the most widely used methods. Therefore, first we call the groups A, B. We consider 4 different permutations of these 2 letters. The 4 permutations of the two letters A and B are: AABB, ABAB, ABBA, BBAA, BABA, BAAB. Each of these is a block of size 4, which includes 2 test group people and 2 control people, we determine randomly by tossing a coin that A, B. Which one is the experiment and which one is the control. For allocation concealment, the letter A (indicator of intervention group 1 and receiving LDX) or B (indicator of intervention group 2 and receiving LDX and TPM) are mentioned in the patient's prescription and then the patient is referred for delivery of drugs.

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 kazeroon azad university

Street address

Alley 15, khoramshahr st, kazeroon, iran

City

Kazeroon

Province

Fars

Postal code

7318853171

Approval date

2022-01-16, 1400/10/26

Ethics committee reference number

IR.IAU.KAU.REC.1400.177

Health conditions studied

1

Description of health condition studied

Binge eating disorder

ICD-10 code

F50-81

ICD-10 code description

Binge eating disorder

Primary outcomes

1

Description

Binge eating score

Timepoint

At first and 3 months after

Method of measurement

Binge eating scale of gormally

Secondary outcomes

1

Description

Body mass index

Timepoint

First and 3 months after treatment

Method of measurement

Meter and weight

Intervention groups**1****Description**

Intervention group: Patients received LDX (n=48) LDX (produced by Tekaje pharmaceutical company) was titrated from 30 mg/day to a maximum of 50mg/day for 12 weeks. Assessment is done at first and then twelve weeks after receiving the treatment

Category

Treatment - Drugs

2**Description**

Intervention group: 45 patients in the second group received LDX (produced by Tekaje pharmaceutical company) as the same 30 mg/day to a maximum of 50mg/day plus TPM (produced by Sobhan pharmaceutical company) with starting dose of 25 mg/day and if tolerated, followed by max dose of 150 mg/day every night for 12 weeks. Assessment is done at first and then twelve weeks after receiving the treatment.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Medical clinics of Shiraz

Full name of responsible person

Mahsa Taghavi

Street address

Psychiatric clinic of Dr Mahsa Taghavi, second floor, Ahoora building, Maaliabad St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7187731139

Phone

+98 71 3634 1771

Email

Dr_mahsataghavi@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mohammad Hossein Marhematizadeh

Street address

Azad Islamic University .Shahid Soleimani blv .Kazeroun

City

Kazeroun

Province

Fars

Postal code

7319866451

Phone

+98 71 4223 0505

Email

Farmokhtarii@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

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**

Islamic Azad University

Full name of responsible person

Mahsa Taghavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Psychiatric clinic of Dr Mahsa Taghavi, second floor, Ahoora building, Maaliabad St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7187731139

Phone

+98 71 3634 1771

Email

Dr_mahsataghavi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahsa taghavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Psychiatric clinic of Dr Mahsa Taghavi,second floor,
Ahoora building, Maaliabad St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7187731139

Phone

+98 71 3634 1771

Email

Dr_mahsataghavi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahsa taghavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Psychiatric clinic of Dr Mahsa Taghavi,second floor,
Ahoora building, Maaliabad St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7187731139

Phone

+98 71 3634 1771

Email

Dr_mahsataghavi@yahoo.com

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

According to Declaration of Helsinki with ethical code
IR.IAU.KAU.REC.1400.177 due to principle of
confidentiality

When the data will become available and for how long

Accessrability 6month after release

To whom data/document is available

Scientific and academic researchers

Under which criteria data/document could be used

according to Declaration of Helsinki with ethical code
IR.IAU.KAU.REC.1400.177 and with respecting to priciples
of confidentiality for scientic researchers,data usage is
permitted

From where data/document is obtainable

1. Refer to or correspond with the research unit of
Kazeroon Islamic Azad University of Kazeroon with postal
code of 7319866451 2.or with following adress mail
,Dr_mahsataghavi@yahoo.com

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

Requests will be reviewed by the research unit of Islamic
Azad University and the scientific officer of the research
within a maximum period of twenty days, and if the
necessary conditions are met, the data file will be
provided to the requesters.

Comments