Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Evaluation of oral Selenium Sulfide effect on treatment of Refractory Obsessive Compulsive Disorder in a Randomized Double Blind Placebo-Controlled Clinical Trial

Protocol summary

Study aim
Evaluation of oral Selenium Sulfide effect on a Refractory Obsessive Compulsive Disorder

Design
Placebo-controlled, parallel groups, double blind, randomized (with random numbers table), phase 3 Clinical Trial

Settings and conduct
In this study patients are divided randomly to two intervention and control groups. intervention group are given fluoxetine 20 mg plus selenium 200 mcg once a day and control group are given fluoxetine 20 mg plus placebo once a day for 6 week. Psychiatrist and patient did not know about groups. study done in ahvaz bardia psychiatry clinic

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 to 62 years, Minimum score of Yale brown questionnaire should be 21, Obtaining written informed consent before entering into the study. Exclusion criteria: Pregnancy, Internal diseases (diabetic patients, hypertension &...), Psychotic patient and mood disorders and neurology diseases, Thinking about suicide, Addiction to alcohol and narcotics, IQ below 80

Intervention groups
Intervention group: Included patients suffer from Obsessive Compulsive Disorder use Selenium Sulfide capsule 200 mcg(manufactory: century, made in USA), once a day, for 6 weeks plus Fluoxetine capsule 20 mg(manufactory: Abidi, made in Iran), once a day, for 6 weeks. Control group: Included patients suffer from Obsessive Compulsive Disorder use placebo capsule(manufactory: Pharmaceutical Technology Development Center of Ahvaz Jundishapur University of Medical Sciences), once a day for 6 weeks plus Fluoxetine capsule 20 mg(manufactory: Abidi, made in Iran), once a day for 6 weeks.

Main outcome variables
Scale of Obsession and Copmpulsion disorder

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180212038699N1**
Registration date: **2018-05-04, 1397/02/14**
Registration timing: **retrospective**

Last update: **2018-05-04, 1397/02/14**
Update count: **0**

Registration date
2018-05-04, 1397/02/14

Registrant information

Name
Mina Andishmand
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-30, 1396/11/10
Expected recruitment end date
2018-04-16, 1397/01/27
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of oral Selenium Sulfide effect on treatment of Refractory Obsessive Compulsive Disorder in a Randomized Double Blind Placebo-Controlled Clinical Trial

Public title

Evaluation of oral Selenium Sulfide effect on treatment of Refractory Obsessive Compulsive Disorder in a Randomized Double Blind Placebo-Controlled Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 62 years Minimum score of Yale brown questionnaire should be 21 Obtaining written informed consent before entering into the study use fluoxetine 20 mg once a day

Exclusion criteria:

Pregnancy Internal diseases (diabetic patients , hypertension & ...) Psychotic patients and mood disorders and neurology diseases Thinking about suicide Addiction to alcohol and narcotics IQ below 80

Age

From **18 years** old to **62 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and researcher both are blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd, Ahvaz Jundishapur University of Medical Sciencesmedical sciences

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-01-27, 1396/11/07

Ethics committee reference number

IR.AJUMS.REC.1396.930

Health conditions studied

1

Description of health condition studied

obsessive compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Obsession and compulsion score in Yale–Brown Obsessive Compulsive Scale (Y-BOCS)

Timepoint

measurement yale brown questionnaire score in the began of first week and in the end of sixth week

Method of measurement

yale brown questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Included patients suffer from Obsessive Compulsive Disorder use Selenium Sulfide capsule 200 mcg (manufactoty: Century, made in USA) once a day for 6 weeks plus Fluoxetine capsule 20 mg (manufactory: Abidi, made in Iran) once a day, for 6 weeks.

Category

Treatment - Drugs

2

Description
Control group: Included patients suffer from Obsessive Compulsive Disorder use placebo capsule (Manufactory: Pharmaceutical Technology Development Center of Ahvaz Jundishapur University of Medical Sciences) once a day, for 6 weeks plus Fluoxetine capsule 20 mg (manufactory: Abidi, made in Iran) once a day for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
دکتر مهدی سیاح برگرد
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Sayah Bargard
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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Full name of responsible person
Mina Andishmand
Position
Student
Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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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

Information related to main consequences can be share

When the data will become available and for how long

access beganning will be 2 month after publish

To whom data/document is available

Medical sciences and health researchers

Under which criteria data/document could be used

All analytical tests can be done

From where data/document is obtainable

Mina Andishmand, andishmand.m@ajums.ac.ir, 09163227484 Mehdi Sayah Bargard, Sayah_bargard@aol.com, 09126348518

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

one week after demand decuments will be given to applicant

Comments