

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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 Compulsion 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)

Phone

+98 61 3374 1298

Email address

andishmand.m@ajums.ac.ir

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

Khuzestan

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 (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.

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

کلینیک روانپزشکی بردیا

Full name of responsible person

دکتر مهدی سیاح برگرد

Street address

East Mihan Ave, Kianpars Blvd, Jordan Physicians Town, First Floor

City

Ahvaz

Province

Khuzestan

Postal code

6136946731

Phone

+98 61 3336 8801

Email

sayahbargard@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Sayah Bargard

Street address

Ahvaz jundishapur university of medical sciences, Golestan boulevard

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3373 8383

Fax

+98 61 3336 1544

Email

andishmand.m@ajums.ac.ir

Web page address

http://www.ajums.ac.ir

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

Street address

Golestan blvd, Ahvaz jondishapur university of medical sciences, Collage of hygiene, second floor, EDC office

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3333 3477

Fax

+98 61 3336 1544

Email

sayahbargard@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mina Andishmand

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Farhang 2 Ave, golestan Blvd, Negin 5 Town, Unit 14

City

Ahvaz

Province

Khouzestan

Postal code

6136956731

Phone

+98 61 3374 1298

Email

andishmand.m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mina Andishmand

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Farhang 2 Ave, Golestan Blvd, Negin 5 Town, Unit 16

City

Ahvaz

Province

Khouzestan

Postal code

613695731

Phone

+98 61 3374 1298

Email

andishmand.m@ajums.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

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 beginning 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 documents will be given to applicant

Comments