

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of zinc sulfate and fluoxetine in comparison with fluoxetine with placebo in children and adolescents with obsessive-compulsive disorder

Protocol summary

Study aim

Investigating the effectiveness of the combination of zinc sulfate and fluoxetine compared to fluoxetine with placebo in children and adolescents with obsessive-compulsive disorder

Design

A clinical trial with the control group, double-blind, randomized, phase 3 on 42 patients, by simple random software.

Settings and conduct

Patients are selected from Besat Hospital and Placement of patients in two groups will be done by simple random method and by software. Then the grouping of the patients is given to the referee specialist and based on the given codes, he puts the necessary drugs in sealed envelopes, which will be numbered on the envelopes, and based on the order of the patient's visits, the corresponding envelope will be given to the patient by the relevant pharmacy. The patient and the doctor do not know about the contents of the envelope. Medicines are placed in capsules in the form of crushed tablets, and the shape of the two medicines is the same.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged 10-17 with obsessive-compulsive disorder Exclusion criteria: having another psychiatric disorder.

Intervention groups

The intervention group is the group to which we give fluoxetine and sulfate. We give fluoxetine and placebo to the control group.

Main outcome variables

Age, gender, marital status, parents' occupation, parents' education, unwanted side effects, obsessive-compulsive symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160530028182N11**

Registration date: **2023-10-10, 1402/07/18**

Registration timing: **retrospective**

Last update: **2023-10-10, 1402/07/18**

Update count: **0**

Registration date

2023-10-10, 1402/07/18

Registrant information

Name

Soleiman Mohammadzadeh

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-16, 1401/05/25

Expected recruitment end date

2023-08-16, 1402/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	necessary drugs in sealed envelopes, which will be numbered on the envelopes, and based on the order of the patient's visits, the corresponding envelope will be given to the patient by the relevant pharmacy. The patient and the doctor do not know about the contents of the envelope. Medicines are placed in capsules in the form of crushed tablets, and the shape of the two medicines is the same.
Scientific title Evaluation of the efficacy of zinc sulfate and fluoxetine in comparison with fluoxetine with placebo in children and adolescents with obsessive-compulsive disorder	Placebo Used
Public title Evaluation of the efficacy of Zinc sulfate and fluoxetine in obsessive_compulsive	Assignment Factorial
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: Age 10-17 years Based on the diagnostic criteria of DSM-5, obsessive-compulsive disorder should be diagnosed in children by a specialist in child and adolescent psychiatry. Exclusion criteria: Existence of accompanying psychiatric disorder except for anxiety disorders and oppositional defiant disorder- Mental retardation based on clinical suspicion History of allergy to zinc sulfate Wilson's disease according to medical statements and documents Liver disease based on medical statements and documents Spending drug treatments in the previous 2 months Suicidal thoughts	Secondary Ids empty
Age From 10 years old to 17 years old	Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics Committee of Kurdistan University of Medical Sciences Street address Qods hospital, Entezam Blvd, sanandaj, Iran City Sanandaj Province Kurdistan Postal code 1344666177
Gender Both	Approval date 2022-07-26, 1401/05/04
Phase 3	Ethics committee reference number IR.MUK.REC.1401.181
Groups that have been masked - Participant - Care provider - Investigator - Outcome assessor	Health conditions studied <u>1</u> Description of health condition studied Obsessive_compulsive disorder ICD-10 code F42 ICD-10 code description Obsessive-compulsive disorder
Sample size Target sample size: 42	Primary outcomes <u>1</u> Description Obsessive compulsive scor in Fua et al.'s 2010 Obsessive Compulsive Questionnaire, Children's Version, 21 items (OCI-CV) Timepoint At the beginning of the study, 4 weeks later, at the end of 8 weeks. Method of measurement
Randomization (investigator's opinion) Randomized	
Randomization description Sampling is done by simple random sampling. Placement or allocation of patients in two groups will be done by simple random method and by software. Then the grouping of the patients is given to the referee specialist and based on the given codes, he puts the necessary drugs in sealed envelopes, which will be numbered on the envelopes, and based on the order of the patient's visits, the corresponding envelope will be given to the patient by the relevant pharmacy. The patient and the doctor do not know about the contents of the envelope. Medicines are placed in capsules in the form of crushed tablets, and the shape of the two medicines is the same.	
Blinding (investigator's opinion) Double blinded	
Blinding description Placement or allocation of patients in two groups will be done by simple random method and by software. Then the grouping of the patients is given to the referee specialist and based on the given codes, he puts the	

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" for this group, patients fluoxetine capsules manufactured by Obeid company for the first week (daily, 5 mg in the morning), the second week (daily, 10 mg in the morning) and the third week (Ravazneh, 20 mg) and then from The fourth week onwards based on the patient's tolerance (Ravazneh, 30 mg) plus zinc sulfate manufactured by Al-Hawi company for the first week (daily, 6.25 mg), for the second week (12.5 mg daily) and for the third week onwards Based on the patient's tolerance (25 mg daily in the morning) is given for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: For this group, patients were given a placebo in capsules similar to Alhawi zinc sulfate containing starch, plus fluoxetine capsules made by Obeid company for the first week (daily, 5 mg in the morning), the second week (daily, 10 mg in the morning). and the third week (Ravazaneh, 20 mg) and then from the fourth week onward based on the patient's tolerance (Ravazaneh, 30 mg) is given.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Solaiman Mohammadzadeh

Street address

Keshavarz Blvd, Mardukh Crossroads, Besat Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Soleimane mohamadzadeh

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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

Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

Soleiman Mohammadzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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