Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of Fluoxetine and Fluvoxamine on child and adolescent depression admitted to Akhavan hospital, Kashan.

Protocol summary

Summary

The primary purpose of this study is to compare the effect of Fluoxetine and Fluvoxamine on child and adolescent depression. In this study, 40 children and adolescents (8-18 years old) who have MDD diagnosis are randomly assigned into two groups to receive either Fluoxetine capsules, 10mg per day, or Fluvoxamine tablets, 25 mg per day. Depression severity of patients using CDI and CGAS scale and drug side effects are assessed at the baseline and 2, 4, and 8 weeks after the interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901093607N1**
Registration date: **2010-06-04, 1389/03/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-06-04, 1389/03/14

Registrant information

Name
Zahra Sepehrmanesh
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Kashan University of Medical Sciences,

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Fluoxetine and Fluvoxamine on child and adolescent depression admitted to Akhavan hospital, Kashan.

Public title

Comparing the effect of Fluoxetine and Fluvoxamine on child and adolescent depression admitted to Akhavan hospital, Kashan.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: IQ more than 70 characterized by psychologist and psychiatrist via clinical interview, age 8-17 years, having major depression without psychotic features based on DSM-IV Exclusion criteria: severe disabling physical illness, other medical problems that counteract with drug use or other antidepressant drugs, Severe mental disorders such as psychotic, bipoular disorders, catatonia symptoms, substance abuse

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences
Street address
Kashan University of Medical Sciences
City
Kashan
Postal code
8713783981
Approval date
2009-01-09, 1387/10/20
Ethics committee reference number
29/5/1/3274/پ

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Depression severity
Timepoint
Baseline and 2, 4, 8 weeks after the intervention
Method of measurement
CDI and CGAS

Secondary outcomes

1

Description
Body weight
Timepoint
Baseline and 2, 4, and 8 weeks after intervention
Method of measurement
Body weight in Kg

2

Description
Adverse effect
Timepoint
Baseline and 2, 4, and 8 weeks after intervention
Method of measurement
any drug adverse effect

Intervention groups

1

Description
Fluovoxamine, Tablets, 25 mg per day, orally for 8 weeks
Category
Treatment - Drugs

2

Description
Flouxetine, Capsules, 10mg per day, orally for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhavan Hospital
Full name of responsible person
Zahra Sepehrmanesh-MD
Street address
Akhavan Hospital, Kashan
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidi
Street address
Kashan university of medical sciences
City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zahra Sepehrmanesh.MD

Position

Assistant Professor of psychiatry

Other areas of specialty/work

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Position

Assistant Professor of Psychiatry, child and Adolescent Psychiatrist

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty