

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 36 1444 3000

Email address

sepehrmanesh-z@kaums.ac.ir

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, bipolar 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

Fluvoxamine, 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

Other areas of specialty/work

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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