

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparative study of the anxiolytic effect of oral ketamine and fluvoxamine in the treatment of children with separation anxiety disorder leads to school avoidance referral to subspecialty medical centers for child and adolescent psychiatry

Protocol summary

Registration timing: **retrospective**

Study aim

Comparison of mean anxiety score in ketamine and fluvoxamine groups before and after treatment by controlling the variables of age, sex, family history and duration of the disorder

Last update: **2022-06-29, 1401/04/08**

Update count: **0**

Registration date

2022-06-29, 1401/04/08

Design

Clinical trial with control group , With parallel groups , No blinding , randomised , Phase 3 design of 100 patients. Double random blocks were used for randomization

Registrant information

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Name of organization / entity

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Settings and conduct

People referring to child and adolescent psychiatric clinics in Isfahan, which include inclusion criteria enter the study. Ketamine up to a maximum dose of 1 mg / kg and Fluvoxamine is increased to a maximum dose of 200 mg. Patients are followed for 16 weeks and Questionnaires are given to patients before treatment and in the eighth and sixteenth weeks.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Children between the ages of 6 and 10 are diagnosed with separation anxiety disorder and avoid school , Lack of a plan or serious suicidal thoughts , No psychiatric comorbid disorders

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-19, 1400/11/30

Intervention groups

Intervention group treated with ketamine , the other group is treated with fluvoxamine as a control group

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Anxiety score, age, sex, family history, duration of the disorder

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211004052670N3**

Registration date: **2022-06-29, 1401/04/08**

Scientific title

Comparative study of the anxiolytic effect of oral ketamine and fluvoxamine in the treatment of children with separation anxiety disorder leads to school avoidance referral to subspecialty medical centers for

child and adolescent psychiatry

Public title

Evaluation of the anti-anxiety effect of ketamine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6 to 10 years
Diagnosis of separation anxiety disorder leads to school avoidance
Conscious consent to participate in the study
No suicidal plans or thoughts at the time of enrollment
Living in Isfahan

Exclusion criteria:

Existence of psychiatric comorbid disorders

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Dual random blocks are used to assign patients to fluvoxamine and ketamine . In this way, both eligible patients are referred to the clinic by their national code and form a block .Then a table of random numbers is used. If the random number was 0-4, the first person was ketamine and the second person was fluvoxamine and if the random number is 5-9, the first person will receive fluvoxamine and the second person will receive ketamine and this process continues until the sample size is sufficient

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences and Health Services , Hezar Jerib St.

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.MUI.MED.REC.1399.1161

Health conditions studied

1

Description of health condition studied

Separation anxiety disorder leads to school refusal

ICD-10 code

F93.0

ICD-10 code description

Separation anxiety disorder of childhood

Primary outcomes

1

Description

Anxiety score based on CATS and SCARED questionnaires

Timepoint

Before treatment and the eighth and sixteenth week

Method of measurement

Childhood Automatic Thought Scale and Screen for Child Anxiety Related Emotional Disorders questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ketamine is started at a dose of 0.1 mg / kg and on weekly visits based on patient tolerance 0.1 mg / kg is increased to a maximum dose of 1 mg / kg

Category

Treatment - Drugs

2

Description

Control group: Fluvoxamine is started at a dose of 25 mg and Depending on the tolerance of patients, it can be increased to a maximum dose of 200 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

Farzaneh Hosseini

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Isfahan University of Medical Sciences and Health Services , Hezar Jerib St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaghayagh hagh jooy javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

farzaneh hosseini

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Full name of responsible person

Farzane Hosseini

Position

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Latest degree

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Other areas of specialty/work

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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

Data can be shared after people are not identified

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any kind of analysis, whether demographic or the accuracy of the results, is unrestricted

From where data/document is obtainable

farzanehoseini@gmail.com

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

Checked as soon as possible

Comments