Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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

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

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.

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

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

Main outcome variables
Anxiety score, age, sex, family history, duration of the disorder

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211004052670N3**
Registration date: **2022-06-29, 1401/04/08**
Registration timing: **retrospective**

Last update: **2022-06-29, 1401/04/08**
Update count: **0**

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

Registrant information

Name
afsaneh karbasi amel

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-02-19, 1400/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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.
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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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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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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