

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effectiveness of etentalin, Ahura hyperactive and risperidone syrups in preschool children with attention deficit hyperactivity disorder (ADHD)

Protocol summary

Study aim

Efficacy of etentalin, Ahura hyperactive and risperidone syrups in preschool children with attention deficit / hyperactivity disorder

Design

Clinical trial, double-blind, randomized, phase 2 on 57 patients, block allocation method was used for randomization.

Settings and conduct

The study is carried out on children suffering from attention deficit hyperactivity disorder who refer to the Ba'ath Hospital clinic in Sanandaj.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 3 to 6 years of age, Attention Deficit Hyperactivity Disorder. Exclusion criteria: Existence of physical illness, Existence of comorbid psychiatric disorder, Mental retardation, Taking drugs for ADHD, History of drug allergy

Intervention groups

The intervention in this study is ethentalin, Ahura hyperactive and risperidone syrups. The first week 0.25 ml once a day, the second week 0.25 ml twice a day and then if tolerated 0.5 ml twice a day More about this source text

Main outcome variables

The person's score is based on Parent's ADHD Rating scale and CGI (Clinical Global Impressions) questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160530028182N9**

Registration date: **2022-12-01, 1401/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-01, 1401/09/10**

Update count: **0**

Registration date

2022-12-01, 1401/09/10

Registrant information

Name

Soleiman Mohammadzadeh

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 87 3323 2168

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dr.mohammadzadeh86@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2023-01-10, 1401/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of etentalin, Ahura hyperactive and risperidone syrups in preschool children with attention deficit hyperactivity disorder (ADHD)

Public title

Effectiveness of etentalin, Ahura hyperactive and risperidone syrups in preschool children with attention

deficit hyperactivity disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The age range of these children is 3 to 6 years According to the DSM-5 diagnostic criterion, the child and adolescent psychiatrist should diagnose ADHD in children.
Exclusion criteria:
 The presence of a serious physical illness, such as a seizure, based on parental history and clinical suspicion Existence of comorbid psychiatric disorder other than confrontational disobedience disorder Mental retardation based on clinical suspicion Taking medications for Attention Deficit Hyperactivity Disorder in the last month History of allergy to ethenalin and Ahura hyperactive

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **57**

Randomization (investigator's opinion)
Randomized

Randomization description
Block allocation method will be used for random allocation in this study. In this way, the patients who meet the criteria for entering the study are considered to be 3 and 4 years old or 5 and 6 years old, and based on the accident, the first person is 3 or 4 years old in one of the treatment groups and the second and third person is 3 or 4-year-old is placed in the second and third treatment groups, respectively, and also based on the accident, the first 5- or 6-year-old person is placed in one of the treatment groups, and the second and third 5- or 6-year-old person is placed in the second and third treatment groups, respectively. and this process will continue until the sample volume is completed.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patient does not know in which treatment group he has been placed, the patient's family also does not know in which treatment group he has been studied due to the fact that their patient receives standard treatment, and also the measurement subjects. The clinical outcome provider does not know how to categorize and how to group the studied subjects. Medicines are prepared and provided in coded packages that only the pharmacist is in the process of coding.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Kurdistan University of Medical Sciences
Street address
 Pasdaran
City
 Sanandaj
Province
 Kurdistan
Postal code
 6617913141
Approval date
 2021-12-28, 1400/10/07
Ethics committee reference number
 IR.MUK.REC.1400.250

Health conditions studied

1

Description of health condition studied
 Attention Deficit Hyperactive Disorder(ADHD)
ICD-10 code
 F90.1
ICD-10 code description
 Attention-deficit hyperactivity disorder, predominantly hyperactive type

Primary outcomes

1

Description
 Parent's ADHD Rating scale Number
Timepoint
 At the beginning of the study (baseline), 2 weeks, 4 weeks and 8 weeks after the study
Method of measurement
 Parent's ADHD Rating scale

2

Description
 Clinical Global Impressions Number
Timepoint
 At the beginning of the study (baseline), 2 weeks, 4 weeks and 8 weeks after the study
Method of measurement
 Clinical Global Impressions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients included in the study during a period of 8 weeks are divided into three groups, the first group of Etentiline syrup (the first week 0.25 ml once a day, the second week 0.25 ml twice a day and after that If tolerated, 0.5 ml twice a day) is given. The patient will be visited at the beginning of the study (baseline), 2 weeks, 4 weeks, and 8 weeks later, and they will be checked for complications and reduction of symptoms, and the ADHD Rating Scale and CGI questionnaire will be completed.

Category

Treatment - Drugs

2

Description

Intervention group: Patients included in the study during a period of 8 weeks are divided into three groups, the second group is hyperactive syrup (first week 0.25 ml once a day, second week 0.25 ml twice a day and after that If tolerated, 0.5 ml twice a day) is given. The patient will be visited at the beginning of the study (baseline), 2 weeks, 4 weeks, and 8 weeks later, and they will be checked for complications and reduction of symptoms, and the ADHD Rating Scale and CGI questionnaire will be completed.

Category

Treatment - Drugs

3

Description

Intervention group: The patients included in the study during a period of 8 weeks are divided into three groups, the third group is Risperidone (0.25 ml once a day in the first week, 0.25 ml twice a day in the second week and then If tolerated, 0.5 ml twice a day) is given. The patient will be visited at the beginning of the study (baseline), 2 weeks, 4 weeks, and 8 weeks later, and they will be checked for complications and reduction of symptoms, and the ADHD Rating Scale and CGI questionnaire will be completed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Quds Hospital Sanandaj

Full name of responsible person

Soliman Mohammadzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Malaki

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Soliman Mohammadzadeh

Position

Associated professor

Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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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

participant individual data

When the data will become available and for how long

6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

researcher working on academic institution

From where data/document is obtainable

dr.mohammadzadeh86@muk.ac.ir

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

2 month

Comments