Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Palmitoylethanolamide as adjunctive treatment of Autism: A double blind and placebo controlled trial

Protocol summary

Summary

The objective of this study is to assess the efficacy of palmitoylethanolamide in the treatment of autism. Forty children between the ages 4 and 12 years with a DSM -5 clinical diagnosis of autistic disorder and who will be outpatients from a specialty clinic for children will be recruited. The children should present with a chief complaint of severely disruptive symptoms related to autistic disorder. Patients will be randomly allocated into palmitoylethanolamide (600 mg BID) + Risperidone (1-3.5mg/day) or Placebo + Risperidone (1-3.5mg/day) for a 10-week, double-blind, placebo-controlled study. Patients will be assessed at baseline and after 5 and 10 weeks of starting medication. The primary outcome measure is the Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (Irritibilityy subscale) and Childhood autism rating scale(CARS) .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702171556N96**
Registration date: **2017-02-20, 1395/12/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name
Shahin Akhondzadeh
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2019-03-05, 1397/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Palmitoylethanolamide as adjunctive treatment of Autism: A double blind and placebo controlled trial

Public title

Palmitoylethanolamide as adjunctive treatment of Autism: A double blind and placebo controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-DSM 5 clinical diagnosis of autistic disorder; 2-children between the ages of 4 and 11 years old; 3- presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone). Exclusion Criteria: 1- Presence of any active medical problem; 2- any other psychiatric diagnosis except for Intellectual disability; 3-history of allergy or intolerance to Risperidone; 4- receiving any psychotropic medications during past two weeks prior to the trial; 5-presence of

hepatic disease resulting impairment of liver function or rising hepatic enzymes; 6-history of seizure during the last 6 months.

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Keshvarz Blvd.

City
Tehran

Postal code

Approval date
2017-02-03, 1395/11/15

Ethics committee reference number
IR.TUMS.VCR.REC.1395.1555

Health conditions studied

1

Description of health condition studied
Childhood autism

ICD-10 code
F84.0

ICD-10 code description
Childhood autism

Primary outcomes

1

Description
Severity of Autism

Timepoint
Baseline and weerks 5 and 10

Method of measurement
Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (irritibility subscale) and Childhood autism rating scale(CARS)

Secondary outcomes

empty

Intervention groups

1

Description
Capsule palmitoylethanolamide600 mg BID+ Tablet Risperidon 1-3.5 mg/day as intervention for 10 weeks

Category
Treatment - Drugs

2

Description
Tablet Risperidone 1-3.5 mg/day +Capsule Placebo as control for 10 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh Hospital

Full name of responsible person
Dr. Shahin Akhondzadeh

Street address
Roozbeh Hospital, South Kargar Sreeet

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Masoud Yunesian

Street address
Tehran University of Medical Sciences, Keshvarz Blvd.

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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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