# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jul 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**
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 5541 2222
**Email address**
s.akhond@sina.tums.ac.ir

**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**
Tehran University of Medical Sciences
**Full name of responsible person**
Prof. Shahin Akhondzadeh
**Position**
Prof. of Clinical Psychopharmacology
**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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Prof. of Clinical Psychopharmacology
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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*