

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Efficacy of pregnenolon in treatment of irritability in teenagers with autism;A double blind and placebo controlled trial

Protocol summary

Study aim

The objective of this study is to assess the efficacy of pregnenolon in the treatment of autism

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be conducted among children with autistic disorder attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: DSM-5 clinical diagnosis of autistic disorder children between the ages of 11 and 17 years old; presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone). Exclusion criteria: presence of any active medical problem other psychiatric diagnosis except for mild to moderate Intellectual disability receiving any antipsychotic medications during past month prior to the trial severe hepatic disease history of allergy to risperidone and intolerance of it; history of seizure requiring change of antiepileptic dose during the last month seizure during the last 6 months.

Intervention groups

The participants will be randomly allocated into two groups. Intervention group(20 persons) will receive pregnenolon (100 mg BID) and risperidone (2.5 to 3.5 mg per day) and control group(20 persons) will receive risperidone(2.5 to 3.5 mg per day) for 10 weeks.

Main outcome variables

Severity of autism

General information

Reason for update

change age

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N112**

Registration date: **2018-07-25, 1397/05/03**

Registration timing: **prospective**

Last update: **2020-04-10, 1399/01/22**

Update count: **1**

Registration date

2018-07-25, 1397/05/03

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

Expected recruitment start date

2018-08-05, 1397/05/14

Expected recruitment end date

2021-08-05, 1400/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of pregnenolon in treatment of irritability in teenagers with autism;A double blind and placebo controlled trial

Public title

Efficacy of pregnenolon in treatment of irritability
inteenagers with autism

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
DSM-5 clinical diagnosis of autistic disorder Teenagers
between the ages of 11and 17 years old Presence of
behavioral problems such as aggression, overactivity or
repetitive behaviors (indication of treatment with
risperidone)
Exclusion criteria:
Presence of any active medical problem Other
psychiatric diagnosis except for mild to moderate
Intellectual disability Receiving any antipsychotic
medications during past monthprior to the trial Severe
hepatic disease History of allergy to risperidone and
intolerance of it History of seizure requiring change of
antiepileptic dose during the last month Seizure during
the last 6 months

Age
From **11 years** old to **17 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random permuted block

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, clinicians and outcome raters will be
blind regarding grouping

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, Qhods St.,
Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-07-14, 1397/04/23

Ethics committee reference number

IR.TUMS.VCR.REC.1397.221

Health conditions studied

1

Description of health condition studied

Autistic disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Severity of autism

Timepoint

Baseline and weeks 5, and 10

Method of measurement

By Aberrant Behavior Checklist-Community(ABC-C)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cap. (100 BID) plus Risperidone (2.5
to 3.5 mg per day) for 10 weeks

Category

Treatment - Drugs

2

Description

Control group: tablet placebo plus Risperidone(2.5 to 3.5
mg per day) for 10 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Prof. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

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msahrai@tums.ac.ir

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

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

Tehran University of Medical Sciences

Full name of responsible person

شاهین آخوندزاده

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

En 5 years from 2021 to 2026

To whom data/document is available

academic researchers

Under which criteria data/document could be used

users should cite the resource of data

From where data/document is obtainable

Prof Shahin Akhondzadeh

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

by E mail

Comments