

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effectiveness of risperidone and aripiprazole in controlling aggression in inpatient adolescents with conduct disorder

Protocol summary

Study aim

Comparison of the effectiveness of risperidone and aripiprazole in reducing aggression in hospitalized adolescents with conduct disorder

Design

A double-blind phase 2 randomized clinical trial on 62 patients

Settings and conduct

Razi Psychiatric hospital, pediatric ward. Patients and researchers do not know the type of medicine.

Participants/Inclusion and exclusion criteria

Age 10-18 years old, conduct disorder, patients admitted to the pediatric psychiatric ward, no bipolar or psychotic disorder, no suicidal idea

Intervention groups

Intervention group 1: Treatment with 1 mg risperidone.
Intervention group 2: treatment with 2.5 mg aripiprazole.

Main outcome variables

Aggression; side effects of medications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210718051932N1**
Registration date: **2021-07-25, 1400/05/03**
Registration timing: **prospective**

Last update: **2021-07-25, 1400/05/03**

Update count: **0**

Registration date

2021-07-25, 1400/05/03

Registrant information

Name

Abbas MAHMOUDI GHARA

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2297 7263

Email address

af2mahmoudi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-31, 1400/05/09

Expected recruitment end date

2021-09-09, 1400/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of risperidone and aripiprazole in controlling aggression in inpatient adolescents with conduct disorder

Public title

Comparison of the effectiveness of risperidone and aripiprazole in controlling aggression in inpatient adolescents with conduct disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Conduct disorder by criteria DSM5 Age 10-12 years old
Patient admitted to the psychiatric ward

Exclusion criteria:

Bipolar disorder Suicidal idea Psychotic disorder Drug allergy to risperidone or aripiprazole Severe medical problems

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in a simple way and by card. The type of intervention is written on the card and is placed in sealed envelopes. According to the sample size, 62 people of both sexes, 32 people in each group, are placed in the list of participants according to the referral order. After entering the study, each person is asked to choose an envelope. According to the predicted sample size, the envelopes are prepared (without replacement).

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient receives the drug (intervention 1 or intervention 2) in enclosed sealed envelopes. The coding is done by one of the project partners and the doctor, evaluator and patient are blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Rehabilitation Sciences and Social Health

Street address

unit 6, No 32, 4th Ave, Mozhdeh Blvd, Hosinabad, Tehran

City

Tehran

Province

Tehran

Postal code

1668847177

Approval date

2021-07-17, 1400/04/26

Ethics committee reference number

IR.USWR.REC.1400.116

Health conditions studied

1

Description of health condition studied

Conduct disorder

ICD-10 code

F91

ICD-10 code description

Conduct disorders

Primary outcomes

1

Description

Aggression

Timepoint

At the end of 1, 2, 4, 6 weeks,

Method of measurement

Bass and Perry Clinical Global Impression scale (CGI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: This group starts treatment with a dose of 1 mg of risperidone and then gradually increases the dose of risperidone to 4 mg due to patient tolerance and no drug side effects over 6 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: The other group is treated with 2.5 mg of Aripiperazole and then gradually according to the patient's tolerance and over 6 weeks, the drug dose of group 2 is increased and the dose of Aripiperazole drug is increased to 20 mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi psychiatric hospital

Full name of responsible person

Nastaran Habibi

Street address

Amin Abad , RaziPsychiatric Hospital

City

Tehran

Province
Tehran
Postal code
1866958891
Phone
+98 21 3340 1220
Fax
+98 21 3340 1600
Email
dr_nhabibi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Hamidreza khankeh
Street address
Kodakyar ave, Daneshjo Blvd, Velenjak
City
Tehran
Province
Tehran
Postal code
1777234562
Phone
+98 21 2218 0083
Email
Hamid.khankeh@ki.se
Web page address
<https://rehabnursing.uswr.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Abbas Mahmoudi Ghara
Position
Resident

Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
32,4 Ave, Mozhdeh Blvd, Hoseinabad square
City
Tehran
Province
Tehran
Postal code
1668847177
Phone
+98 21 2297 7263
Email
af2mahmoudi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Nastaran Habibi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Kodakyar ave ,Velanjak, University of Social Welfare and Rehabilitation Sciences
City
Tehran
Province
Tehran
Postal code
1772356872
Phone
+98 21 2218 0083
Email
dr_nhabibi@yahoo.com
Web page address
<https://rehabnursing.uswr.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Abbas Mahmoudi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
32 accesory, 4th Ave, Mozhdeh street, Hoseinabad

square, Tehran

City

Tehran

Province

Tehran

Postal code

1668847177

Phone

+98 21 2297 7263

Email

af2mahmoudi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available