Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Comparison of effectiveness and complications Different doses of propranolol with methylphenidate in children with ADHD

Protocol summary

Summary

Among patients referred to psychiatric Golestan Hospital, Ahwaz, which have ages 6 to 12 years, 30 children with hyperactivity disorder, who diagnosed by a psychiatrist with clinical interview, based on the parent kind of revised text of the fourth statistical detection guide, was selected and randomly divided into two groups. Companions to all the participants are given sufficient explanation about the plan and then informed consent is obtained. The first group is given Methylphenidate and propranolol with the dose of 10 to 20 mg per day and the second group is given Methylphenidate and propranolol, with the dose of 20 to 40 mg per day. Methylphenidate, starts to the amount of approximately 0.3 Mg per kg of body weight in both morning and afternoon and increases based on side effects and clinical profile to approximately 1 mg per kg body weight per day. Before treatment and at the end of second and fourth weeks, blood pressure, weight and heart rate in children are also measured and recorded. Before treatment and at the end of second and fourth weeks, treatment response is measured based on Conners test as well and in this intervals, every side effects is measured based on side effects Czech list, And finally the collected data is analyzed statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204188317N1**
Registration date: **2012-04-16, 1391/01/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-16, 1391/01/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jondi Shapur University of Medical Sciences

Expected recruitment start date

2011-12-21, 1390/09/30

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness and complications Different doses of propranolol with methylphenidate in children with ADHD

Public title

Effects of different doses of propranolol with methylphenidate in the treatment of ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Having diagnostic criteria based on the revised text of the fourth statistical detection guide to identify mental disorders and tests Conners (Test for

diagnosing hyperactivity disorder and it’s grading), In this study, cases of moderate and severe impairment (score greater than or equal to 20 conners) are studied. 2-Age between 6 to 12 years. 3-Obtaining informed consent from parents. Exclusion criteria: 1-Other psychiatric disorder based on a criteria based DSM IV_TR 2-Mental retardation. 3-Having a history of seizures. 4-Any medical problems, including the use of beta blockers and methylphenidate such as asthma, cardiovascular problems, diabetes, history of allergy to drugs, the tic

Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Jundi Shapur University of Medical Sciences, Ahwaz
Street address
Ahvaz - City University - Department of Research & Technology Of Medical Sciences, Ahwaz Jondi Shapur - Ground Floor
City
ahwaz
Postal code
15794-61357
Approval date
2011-10-12, 1390/07/20
Ethics committee reference number
ETH-235

Health conditions studied

1

Description of health condition studied
Attention deficit hyperactivity disorder
ICD-10 code
F90.0
ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
The amount of improvement of ADHD symptoms
Timepoint
Before the intervention,Two weeks after intervention,Four weeks after intervention
Method of measurement
Conners test

Secondary outcomes

1

Description
Side effects
Timepoint
Before the intervention,Two weeks after intervention,Four weeks after intervention
Method of measurement
Onset of symptoms based on parents day comment

2

Description
The time for improving the symptoms of disorder attention deficit- hyperactivity disorder
Timepoint
The starting day reduction of symptoms
Method of measurement
Onset of symptoms based on parents day comment

Intervention groups

1

Description
The study is performed in two groups. The first group is given Methylphenidate propranolol with the dose of 10-20 10 mg per day and the second group is given Methylphenidate propranolol, with the dose of 40-20 mg per day. Methylphenidate, starts to the amount of approximately 3 /. Mg per kg of body weight in both morning and afternoon, and increases based on side effects and clinical profile to approximately 1 mg per kg body weight per day.The drug is prescribed for one month.
Category
Treatment - Drugs

2

Description
The second group is given Methylphenidate propranolol

with the dose of 10-20 10 mg per day and the second group is given Methylphenidate propranolol, with the dose of 40-20 mg per day. Methylphenidate, starts to the amount of approximately 3 /. Mg per kg of body weight in both morning and afternoon, and increases based on side effects and clinical profile to approximately 1 mg per kg body weight per day.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Golestan hospital pediatric psychiatric clinic
Full name of responsible person
Dr. Ashraf Tashakori
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mostafa Feghi
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University city, Ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Ahvaz 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
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Person responsible for scientific inquiries

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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