Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluaqtion and comparison of therapeutic effects of risperidone and buspirone in treating problem behaviours in children with phenylketonuria

Protocol summary

Summary

24 child with known PKU aged between 2 to 16 yrs-old that suffer from problem behavior treated cross-overally with risperidone and buspirone for 8-weeks and their therapeutic responses rated with NISONGER child behavior rating form(mental retarded child version) and clinical global improvement(CGI)form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011412131N1**
Registration date: **2013-05-06, 1392/02/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-06, 1392/02/16

Registrant information

Name
Abdi Ghajarpour
Name of organization / entity
Hamedan University of Medical Scienses
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Scienses resarch and technology adjutancy

Expected recruitment start date

2012-04-17, 1391/01/29

Expected recruitment end date

2013-05-26, 1392/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluaqtion and comparison of therapeutic effects of risperidone and buspirone in treating problem behaviours in children with phenylketonuria

Public title

Evaluation of risperidone and buspirone in treatment of problem behaviors in children with pku

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: known case of PKU aged 2 to 16 yrs-old that pediatric psychiatrist comment drug therapy for problem behavior and parents documented consent form. Exclusion criteria: serious drug side effects; need to another psychotropic drug; known hypersensitivity to risperidone and buspirone and no clinical benefit of risperidone and buspirone in the past.

Age

From **2 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamedan University of Medical Sciences
Street address
Besat hospital
City
Hamedan
Postal code
Approval date
2011-08-20, 1390/05/29
Ethics committee reference number
1827-9-35-16-د-پ

Health conditions studied

1

Description of health condition studied
phenylketonuria
ICD-10 code
E70.0
ICD-10 code description
Disorders of aromatic amino-acid metabolism

Primary outcomes

1

Description
compliant/calm
Timepoint
2 month
Method of measurement
NISONGER child behaviour rating form

2

Description
Conduct problem
Timepoint
2 month
Method of measurement
NISONGER child behavior rating form

3

Description
Insecure/Anxious
Timepoint
2 month
Method of measurement
NISONGER child behaviour rating form

4

Description
Overly sensitive
Timepoint
2 month
Method of measurement
NISONGER child behaviour rating form

5

Description
Hyperactive
Timepoint
2 month
Method of measurement
NISONGER child behaviour rating form

6

Description
Self-injury/stereotypic
Timepoint
2 month
Method of measurement
NISONGER child behaviour rating form

7

Description
Self-isolated/Ritualistic
Timepoint
2 month
Method of measurement
NISONGER child behaviour rating form

8

Description
Adaptive/social
Timepoint
2 month
Method of measurement
NISONGER child behaviour rating form

Secondary outcomes

1

Description
Clinical global improvement rate
Timepoint
2 and 4 months
Method of measurement
Clinical global improvement form

Intervention groups

1

Description
Control group includes 13 child with pku between ages 2 to 16 yrs-old that recieve risperidone with gradually increasing doses up to1.5 mg (and over 30-kg weight with 3 mg) per day for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group include 13 child with phenylketonuria between 2 to 16 yrs -old that recieve buspirone with dose of 2.5mg up to7.5 mg (over 30-kg weight up to 15mg) per day for 8weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Dr Abdi Ghajarpour
Street address
Besat hospital
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
hamedan university of medical sciences
Full name of responsible person
Dr heydar tavilani
Street address
shahid fahmide blu.
City
hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
hamedan 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
Hamedan University of Medical Sciences
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MD, Resident of pediatric
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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