

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Evaluation 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 Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1835 0107

###### Email address

a.ghajarpour@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Hamedan University of Medical Sciences research 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

Evaluation 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-پ-د

**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 to 1.5 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 to 7.5 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

**Full name of responsible person**

Dr Abdi Ghajarpour

**Position**

MD, Resident of pediatric

**Other areas of specialty/work**

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**Full name of responsible person**

Dr Afshin Fayyazi

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## Person responsible for updating data

### Contact

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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*