

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison the influence of verbal and non-verbal methods of parent education on the control of blood phenylalanine levels in children with phenylketonuria (PKU)

#### Protocol summary

##### Summary

The purpose of this study is evaluation the effect of parents education in verbal and non-verbal methods to control the amount of phenylalanine of the serum of children which suffering from phenylketonuria. The study population is 45 family and children which suffering from phenylketonuria with 1-18 years old in which referred to PKU clinic of Abuzar hospital. Inclusion criteria: Having a sick child that stricken to PKU; having a file at PKU clinic of Abuzar hospital; Pediatric patient ranging from 1 to 18 years old; The parents learning ability; Having the main care provider at home. Exclusion criteria: absence of parents for at least two training sessions. First, parents by completing questionnaires ,their knowledge about phenylketonuria ,in which has been finalized by professors of university of medical sciences, assessing their awareness of the phenylketonuria (PKU), and according to their scores, randomly they will be divided into two groups , intervention and control. The intervention group contains two group, 15 each, one group using verbal method within 8 sessions , 2 hours each, within one month; and the other group at the same period using non-verbal training method with booklet and pamphlets for one month and follow up, will be trained, The control group consisted of 15 member in which there is no intervention for this group. The Parents of both intervention and control groups after one month will fill up the knowledge questionnaires and their children phenylalanine level, before and after the intervention will be recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012122911923N1**  
Registration date: **2013-01-31, 1391/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-01-31, 1391/11/12

##### Registrant information

###### Name

Akram Hematipour

###### Name of organization / entity

Ahvaz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1373 8302

###### Email address

hematipour.a@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz University of Medical Sciences.

##### Expected recruitment start date

2012-08-22, 1391/06/01

##### Expected recruitment end date

2012-10-22, 1391/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the influence of verbal and non-verbal methods of parent education on the control of blood phenylalanine levels in children with phenylketonuria

(PKU)

**Public title**

Comparison the influence of verbal and non-verbal methods of parent education on the control of blood phenylalanine levels in children with phenylketonuria (PKU)

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Having a sick child that stricken to PKU; having a file at PKU clinic of Abuzar hospital; Pediatric patient ranging from 1 to 18 years old; The parents learning ability; Having the main care provider at home. Exclusion criteria: absence of parents for at least two training sessions.

**Age**

From **1 year** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ahvaz University of Medical Sciences

**Street address**

Esfand Alley, Golestan Blvd, Ahvaz, Khuzestan

**City**

Ahvaz

**Postal code****Approval date**

2012-06-26, 1391/04/06

**Ethics committee reference number**

u-91129

**Health conditions studied****1****Description of health condition studied**

Disease, phenylketonuria (PKU)

**ICD-10 code**

E70

**ICD-10 code description**

Disorders of aromatic amino-acid metabolism

**Primary outcomes****1****Description**

Serum phenylalanine levels

**Timepoint**

A month before the intervention, one month after intervention

**Method of measurement**

Blood Tests

**2****Description**

Parental awareness

**Timepoint**

A month before the intervention, one month after intervention

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The intervention group: personal training (face and speech), two two-hour sessions in a week for 4 weeks

**Category**

Treatment - Drugs

**2****Description**

no intervention

**Category**

Treatment - Drugs

**3****Description**

The intervention group: in-person training (training manuals and pamphlets) for a period of one month, every week, and follow up by phone

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

PKU clinic in Abuzar hospital

**Full name of responsible person**

Doctor Aminzadeh Majid, Endocrinology and Metabolism PKU clinics and hospitals charge Abuzar

**Street address**

Abuzar Hospital, Ahvaz, Khuzestan.

**City**

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ahvaz University of Medical Sciences

**Street address**

Esfand Alley, Golestan Blvd, Ahvaz, Khuzestan

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

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

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Akram Hemmati pour

**Position**

Senior Nursing Student Orientation Pediatrics, Ahvaz University of Medical Sciences, School of Nursi

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Hoshang Alijani

**Position**

Pediatric Nursing Department Orientation and Board

Member of Ahvaz University of Medical Sciences

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## Person responsible for updating data

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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*