

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+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

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no

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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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Position

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Web page address

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