

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of educational - nutritional Interventions on micronutrients and Phenylalanine in patients with Phenylketonuria

Protocol summary

Study aim

Determining effect of educational - nutritional Interventions on micronutrients and phenylalanine in patients with phenylketonuria in Hamadan province

Design

Before & After Clinical Trial, with parallel groups

Settings and conduct

This study will be carried out at the Phenyl Ketronyuria Clinic of Besat Hospital in Hamadan. carers will be trained , and dietary foods for patients and instructions of diet will be provided for target group, The test will include phenylalanine and micronutrients will be performed before and after intervention in the province's reference laboratory .

Participants/Inclusion and exclusion criteria

Inclusion criteria: - A 1-12 year old child with phenyl ketoneuria; - Active file of the patient's care; - Informed consent of parents; Exclusion criteria: -Malignant phenylketonuria; -Not receiving special diet;

Intervention groups

The study consists of two intervention groups. One group will receive counseling and training for special diet and the other group will receive free specialty foods for patients with phenylketonuria

Main outcome variables

Blood phenylalanine- Hemoglobin - Hematocrit - Vitamin D - vitamin B12

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180506039548N1**

Registration date: **2018-06-06, 1397/03/16**

Registration timing: **prospective**

Last update: **2018-06-06, 1397/03/16**

Update count: **0**

Registration date

2018-06-06, 1397/03/16

Registrant information

Name

Reza Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3424 5412

Email address

r.zamani@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational - nutritional Interventions on micronutrients and Phenylalanine in patients with Phenylketonuria

Public title

The effect of educational - nutritional Interventions on micronutrients and phenylalanine in patients with phenylketonuria

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

A 12-12 year old child with phenylketoneuria Active file of the patient's case under care Informed consent of parents

Exclusion criteria:

Malignant phenylketonuria Not receiving special diet

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

All patients with phenylketonuria 1-12 will be assigned into two groups through Simple randomization.

Randomized method: Simple randomization. Randomized Unit: Individual. Randomization Tool: Software. Hiding: All participants in code study are assigned.

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**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences,Fahmideh street

City

Hamadan

Province

Hamadan

Postal code

6517659114

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.UMSHA.REC.1397.11

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

Phenylketonuria

ICD-10 code

E70.0

ICD-10 code description

Classical phenylketonuria

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

Blood phenylalanine

Timepoint

Before and after intervention

Method of measurement

Blood test

2**Description**

Blood Vitamin D

Timepoint

Before and after intervention

Method of measurement

Blood test

3**Description**

Blood Vitamin B12

Timepoint

Before and after intervention

Method of measurement

Blood test

4**Description**

Blood zinc

Timepoint

Before and after intervention

Method of measurement

Blood test

5**Description**

Blood hemoglobin

Timepoint

Before and after intervention

Method of measurement

Blood test

6**Description**

Blood hematocrit

Timepoint

Before and after intervention

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group receive counseling and training for special diet

Category

Behavior

2

Description

Intervention group: This group receive free specialty foods for patients with phenylketonuria

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Be'sat Hospital

Full name of responsible person

Mitra Javedan

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Motahari Boulevard

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6514845411

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mehrsam473@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Zamani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the use of data in future design studies, no plans
have been devised to disseminate information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available