Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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
Street address
Motahari Boulevard
City
Hamadan
Province
Hamadan
Postal code
6514845411
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+98 81 3264 0033
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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
Street address
Hamadan University of Medical Sciences,Fahmideh street
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s-bashirian@umsha.ac.ir
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

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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