Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of low protein pasta with regular pasta on blood phenylalanine levels in children with phenylketonuria

Protocol summary

Study aim
Comparison of the effect of low protein pasta with regular pasta on blood phenylalanine levels in children with phenylketonuria

Design
A clinical trial with the control group, cross-over, randomized, without blinding on 30 patients with phenylketonuria

Settings and conduct
Location: Emam-Ali Hospital, Karaj, Alborz Records and medical history of all patients are available. After contacting eligible patients and obtaining consent to participate in the project, participants are randomly divided into two groups. The first group uses the standard phenylketonuria diet for one week without special diet products and the second group uses the standard diet with diet products for one week. After washout period, the group intervention shifts. The duration of the intervention will be 3 weeks. All patients are evaluated at the beginning and end of each week for food intake, blood phenylalanine levels, body composition, diet compliance and satisfaction, and biochemical indicators.

Participants/Inclusion and exclusion criteria
Children with phenylketonuria aged 1 to 18 years are included in the study. Criteria for non-inclusion: suffering from other underlying diseases, consumption of Kovan drug, unwillingness to consume pasta, parents' dissatisfaction with participation in the research project.

Intervention groups
The first group uses the standard phenylketonuria diet for one week without special diet products and the second group uses the standard diet containing special low-protein pasta for one week. Then for a week all patients will be free to choose daily food (wash out). In the next step, the group intervention shifts.

Main outcome variables
Body composition Food intake Diet compliance and satisfaction Blood tests including: Phe and Tyr amino acid; CBC; FPG; Uric acid; Creatinine; Cholesterol; LDL; HDL; Triglyceride; Ferritin; B12; Folic acid; Homocysteine; 25-OH-VitaminD; Zinc; Prealbumin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210427051104N1**
Registration date: **2021-06-26, 1400/04/05**
Registration timing: **prospective**

Last update: **2021-06-26, 1400/04/05**
Update count: **0**

Registration date
2021-06-26, 1400/04/05

Registrant information

Name
Hoda Derakhshanian

Name of organization / entity
Alborz University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of low protein pasta with regular pasta on blood phenylalanine levels in children with phenylketonuria

Public title
Evaluation of the effectiveness of low protein and low phenylalanine products (Zarmacaron) in the diet of people with phenylketonuria
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children with phenylketonuria
Exclusion criteria:
Reluctance to consume pasta Suffering from other underlying diseases Taking KUVAN drug Parents' dissatisfaction with participation in the research project
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: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
In this crossover study, each patient receives two different treatments and is tested twice.
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are divided into two groups by the randomized block method. The blocks will be selected in six and random numbers will be generated by Excel software to select the blocks.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Vice chancellor for research and technology, Alborz University of medical Sciences, Saffarian St., Golshahr Ave., Karaj, Alborz
City
Karaj
Province
Alborz
Postal code
3198764653
Approval date
2021-03-06, 1399/12/16
Ethics committee reference number
IR.ABZUMS.REC.1399.338

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
Phenylalanine
Timepoint
Day 0, 7, 14 and 21 of intervention
Method of measurement
High Performance Liquid Chromatography

Secondary outcomes

1

Description
Diet compliance and satisfaction
Timepoint
Day 0, 7, 14 and 21 of intervention
Method of measurement
Questionnaire

2

Description
Body composition
Timepoint
Day 0, 7, 14 and 21 of intervention
Method of measurement
Body analyzer - Inbody270

Intervention groups

1

Description

Intervention group: first receives the standard diet with low phenylalanine pasta and then the standard diet without diet products ---The first group uses the standard phenylketonuria diet with low phenylalanine pasta for one week. Then for a week all patients will be free to choose daily food (rest period similar to normal pre-study diet). Next, participants use a standard diet without diet cereal products for a week. It should be noted that all diets are designed equally in terms of the amount of phenylalanine. Therefore, the duration of the intervention will be 3 weeks. All patients are evaluated for food intake and blood phenylalanine levels at the beginning of the study, at the end of the first week, at the end of the second week, at the end of the study. Tests for patients include: evaluation of body composition using body analyzer, evaluation of food intake using a food record questionnaire, and blood tests, including serum phenylalanine level, which is performed 4 times per patient. Other biochemical indicators that are tested only at the beginning of the study to assess the nutritional status of patients includes: Tyr amino acid, CBC, FPG, Uric acid, Creatinine, Cholesterol, LDL, HDL, Triglyceride, Ferritin, B12, Folic acid, Homocysteine, 25-OH-VitaminD, Zinc, Prealbumin. Also, the level of satisfaction and adherence of the people to the diet in different phases is measured and scored.

Category

Lifestyle

2

Description

Control group: first receives the standard diet without diet products and then the standard diet with low phenylalanine pasta--- Control group: first receives the standard diet without diet products and then the standard diet with low phenylalanine pasta---The first group uses the standard phenylketonuria diet without diet cereal products for one week. Then for a week all patients will be free to choose daily food (rest period similar to normal pre-study diet). Next, participants use a standard diet with low phenylalanine pasta for a week. It should be noted that all diets are designed equally in terms of the amount of phenylalanine. Therefore, the duration of the intervention will be 3 weeks. All patients are evaluated for food intake and blood phenylalanine levels at the beginning of the study, at the end of the first week, at the end of the second week, at the end of the study. Tests for patients include: evaluation of body composition using body analyzer, evaluation of food intake using a food record questionnaire, and blood tests, including serum phenylalanine level, which is performed 4 times per patient. Other biochemical indicators that are tested only at the beginning of the study to assess the nutritional status of patients includes: Tyr amino acid, CBC, FPG, Uric acid, Creatinine, Cholesterol, LDL, HDL, Triglyceride, Ferritin, B12, Folic acid, Homocysteine, 25-OH-VitaminD, Zinc, Prealbumin. Also, the level of satisfaction and adherence of the people to the diet in different phases is measured and scored

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam-Ali Hospital

Full name of responsible person
Solaleh Sanei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Alborz University of Medical Sciences

Full name of responsible person
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A

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz University of Medical Sciences

Proportion provided by this source

30

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

2

Sponsor

Name of organization / entity

Zarmacaron

Full name of responsible person

Morteza Soltani, Mohsen Amini

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Email

info@zarmacaron.ir

Web page address

https://www.zarmacaron.com/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zarmacaron

Proportion provided by this source

70

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Hoda Derakhshanian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Decide on a case by case basis
From where data/document is obtainable
Principal Investigator Dr. Hoda Derakhshanian h.derakhshanian@gmail.com
What processes are involved for a request to access data/document
After coordination with the principal investigator, the information will be available within one month.
Comments