

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Consumption of High calorie-Fruit Juice Fortified with Vitamin C on Protein Intake, Oxidative Stress and Amino Acid Profile of Children with Propionic Acidemia.

Protocol summary

Study aim

Determination of high-calorie vitamin C-fortified fruit juice intake on children with PA

Design

Two-arm, parallel group, single blind, randomized controlled trial (using number random table)

Settings and conduct

Research place: Emam Reza specialized and sub-specialized clinic Following selection of qualified individuals, the complete study process will be explained to the parents and written informed consent will be obtained. Information will be collected by the researchers. Participants will then be randomly assigned to intervention and control groups. Prior to starting the intervention, subjects in both groups will receive an individual low-protein diet for 7 days. At the end of the week, parents will be asked to bring their children to the lab after a 2-4-hour fasting period. Blood samples will then be taken for serum separation and measurements of protein status-, oxidative stress-, and plasma amino acid profiles. Fruit juices will be provided to the parents of both study groups. At the end of the 12-week-intervention period, blood tests and anthropometric measurements will be repeated. To ensure the compliance, serum levels of vitamin C will be measured both at the beginning and endpoint of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 2-6 years of age Suffering from propionic acidemia (PA) according to metabolic panel test Confirmation of the disease by genetic test (if possible) Parental consent for participation in the study and daily intake of fruit juice Monthly cycles of one-week metronidazole therapy (10-20 mg/kg). Exclusion criteria: Parental dissent for participation in the study and daily intake of fruit juice

Intervention groups

Control group: receiving natural fruit juice Intervention

group: receiving natural high-calorie fruit juice fortified with vitamin C

Main outcome variables

Plasma amino acid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121019011168N3**

Registration date: **2018-08-19, 1397/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-19, 1397/05/28**

Update count: **0**

Registration date

2018-08-19, 1397/05/28

Registrant information

Name

Seyedeh Maryam Abdollahzadeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3649 1126

Email address

abdolahsm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Education, Shiraz University of Medical Sciences

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2018-11-11, 1397/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Consumption of High calorie-Fruit Juice Fortified with Vitamin C on Protein Intake, Oxidative Stress and Amino Acid Profile of Children with Propionic Acidemia.

Public title

The Effect of Consumption of High calorie-Fruit Juice Fortified with Vitamin C in the Management of Propionic Acidemia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 2-6 years of age Suffering from propionic acidemia (PA) according to metabolic panel test
Confirmation of the disease by genetic test (if possible)
Parental consent for participation in the study and daily intake of fruit juice
Monthly cycles of one-week metronidazole therapy (10-20 mg/kg).

Exclusion criteria:

Parental dissent for participation in the study and daily intake of fruit juice

Age

From **2 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly allocated into two groups of control and intervention using number random table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will be blinded by the use of the same-shape package of fruit-juices to treatment allocation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Committee of the Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2017-12-10, 1396/09/19

Ethics committee reference number

IR.SUMS.REC.1396.135

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

Propionic acidaemia

ICD-10 code

E71.1

ICD-10 code description

Other disorders of branched-chain amino-acid metabolism_Propionic acidaemia

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

Amino acid profile

Timepoint

Before intervention, after intervention

Method of measurement

HPLC method

2**Description**

Ammonia

Timepoint

Before intervention, after intervention

Method of measurement

Spectrophotometry

Secondary outcomes**1****Description**

Serum vitamin C

Timepoint

Before intervention, after intervention

Method of measurement

HPLC method

2**Description**

Serum glutathione peroxidase

Timepoint

Before intervention, after intervention

Method of measurement

Enzymatic, colorimetric method

3**Description**

Serum superoxide dismutase

Timepoint

Before intervention, after intervention

Method of measurement

Enzymatic, colorimetric method

4**Description**

Total antioxidant capacity

Timepoint

Before intervention, after intervention

Method of measurement

Enzymatic, colorimetric method

5**Description**

Serum total protein

Timepoint

Before intervention, after intervention

Method of measurement

Autoanalyzer, colorimetric method

6**Description**

Serum Albumin

Timepoint

Before intervention, after intervention

Method of measurement

Autoanalyzer, colorimetric method

7**Description**

Serum Prealbumin

Timepoint

Before intervention, after intervention

Method of measurement

Immunoturbidimetric method

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

Consumption of natural high calorie-fruit Juice fortified

with vitamin C for 12 weeks; Intervention group

Category

Treatment - Other

2**Description**

Consumption of natural fruit Juice for 12 weeks; Control group

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Metabolic Clinic, Emam Reza specialized and sub-specialized clinic

Full name of responsible person

Seyedeh Maryam Abdollahzadeh, Ph.D. Candidate; Shiraz University of Medical Sciences

Street address

Emam Reza specialized and sub-specialized clinic, Namazi Sq.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Zohreh Mostafavipour (Vice Chancellor for Education, Shiraz University of Medical Sciences)

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Seyedeh Maryam Abdolazadeh

Position

Ph.D. Candidate of Nutrition Sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Dr. Zohreh Mazloom

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Professor in Nutrition Sciences

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

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Position

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Latest degree

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Web page address**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

There is no program for its release

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

Yes - There is 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

Title and more details about the data/document

Report of the clinical study

When the data will become available and for how long

One year after finishing the data collection

To whom data/document is available

All researchers

Under which criteria data/document could be used

In order to complete research on the particular rare disease

From where data/document is obtainable

The corresponding author of the published article

What processes are involved for a request to access data/document

Sending an email to the corresponding author of the published article

Comments