# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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.
**City**
Shiraz
**Province**
Fars
**Postal code**
71348714737
**Phone**
+98 71 3212 7001
**Email**
emamreza@sums.ac.ir

## 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)
**Street address**
Shiraz University of Medical Sciences, Zand St.
**City**
Shiraz
**Province**
Fars
**Postal code**
7134814336
**Phone**
+98 71 3233 2093
**Email**
madopzsh@sums.ac.ir
**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 Abdolahzadeh
**Position**
Ph.D. Candidate of Nutrition Sciences
**Latest degree**
Master
**Other areas of specialty/work**
Nutrition
**Street address**
School of Nutrition and Food Sciences, Razi Blvd.
**City**
Shiraz
**Province**
Fars
**Postal code**
71645-111
**Phone**
+98 71 3725 1001
**Fax**
**Email**
abdolahsm@sums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Zohreh Mazloom
**Position**
Professor in Nutrition Sciences
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
School of Nutrition and Food Sciences, Razi Blvd.
**City**
Shiraz
**Province**
Fars
**Postal code**
71645-111
**Phone**
+98 71 3725 1001
**Fax**
**Email**
zohreh.mazloom@gmail.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Seyedeh Maryam Abdolahzadeh
**Position**
Ph.D. Candidate in Nutrition Sciences
**Latest degree**
Master
**Other areas of specialty/work**
Nutrition
**Street address**
School of Nutrition and Food Sciences, Razi Blvd.
**City**
Shiraz
**Province**
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**Postal code**
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**Phone**
+98 71 3725 1001
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abdolahsm@sums.ac.ir
**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**