

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating the effect of albumin consumption on malnutrition indices in primary school children with mild to moderate underweight

Protocol summary

Study aim

Determining the effect of consuming pasteurized cow's milk fortified with albumin in underweight primary school children in Yasuj.

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. The software was used for randomization

Settings and conduct

Participants will be selected by two-stage random sampling from the list of all primary schools in Yasuj city, Iran. In this way, first, a list of all primary schools in Yasuj will be prepared, and after making the relevant arrangements with the school principal, the parents of the students will be contacted. For all students whose parents have given their final consent, the anthropometric parameters (height and weight) will be measured and entered into the Anthro WHO software to calculate the standard score (Z score). According to the definition of the World Health Organization, $-3 \leq z\text{-score} \leq -1$ was considered as mild to moderate underweight. This stage will continue until the number of eligible children reaches 60.

Participants/Inclusion and exclusion criteria

Elementary students, lack of underlying disease affecting student development, do not take any dietary supplements or do not follow a special diet for 6 months before the study, mild to moderate underweight

Intervention groups

Participants in the intervention group receive 200 cc cow's milk with 10gr albumin powder per day and in the control group receive 200 cc cow's milk with 10gr cornstarch powder per day for 12 weeks.

Main outcome variables

Dietary intake; body composition indices; anthropometric indices, Z-Score weight-for-age, Z-Score BMI-for-age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210109049971N1**

Registration date: **2021-01-18, 1399/10/29**

Registration timing: **retrospective**

Last update: **2021-01-18, 1399/10/29**

Update count: **0**

Registration date

2021-01-18, 1399/10/29

Registrant information

Name

Hajar Davarpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 2283

Email address

davarpanah.nut65@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

2020-07-05, 1399/04/15

Actual recruitment end date

2020-08-10, 1399/05/20

Trial completion date

2020-11-10, 1399/08/20

Scientific title

Evaluating the effect of albumin consumption on malnutrition indices in primary school children with mild to moderate underweight

Public title

Albumin protein and malnutrition indices in primary school children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Elementary students Lack of underlying disease affecting student development such as diabetes, hypothyroidism, liver and kidney problems Do not take dietary supplements or do not follow a special diet for at least 6 months before the study Mild to moderate underweight

Exclusion criteria:**Age**

From **7 years** old to **13 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will randomly be allocated in a 1:1 ratio, to intervention and control groups. Randomization will be conducted by random allocation software to allocate patients using blocked randomization with a fixed block size of 4. Randomization will be done by an investigator who had no clinical involvement in the trial. Furthermore, other procedures including enrollment, sequence generation, allocation concealment, and randomization process will all be performed by the principal investigators.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind patients, the interventions in both groups will be identical in appearance and color. The interventions will be coded differently in each group to blind the investigator.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Blvd

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2020-06-29, 1399/04/09

Ethics committee reference number

IR.SUMS.REC.1399.483

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

Primary school children with mild to moderate underweight

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Z-Score Body mass index-for-age

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Anthropometric indicators through scales and tape meters; Body composition with BIA device.

Secondary outcomes

empty

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

Intervention group: Participants in this group receive 200 cc cow's milk with 10gr albumin powder per day for 12 weeks

Category

Treatment - Other

2**Description**

Control group: Participants in this group receive 200 cc cow's milk with 10gr cornstarch powder per day for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Primary schools in Yasuj city

Full name of responsible person

Hajar Davarpanah

Street address

Abshaar Blvd

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Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

0

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Siavash Babajafari

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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

Siavash Babajafari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

Student

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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)

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

Total data after unidentifiable individuals by the researcher is shareable

When the data will become available and for how long

The access period starts 6 months after publishing the results.

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to investigate and perform further analyzes

From where data/document is obtainable

Siavash Babajafari 09177871387

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

After sending the request and reviewing the request by the corresponding author, the data will be provided to you

Comments