

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study The Effect of Enteral Nutrition with Home-made Formula Compared with Commercial Formulas on Tolerance, Blood Factors and Clinical Symptoms in Children Aged 2-18 Years Admitted to PICU

Protocol summary

Study aim

Study The effect of Enteral Nutrition with Home-made Formula Compared with Commercial Formulas on Tolerance, Blood Factors and Clinical Symptoms in Children Aged 2-18 Years Admitted to PICU

Design

A clinical trial with a control group, with parallel groups, single blind, randomized, on 24 patients Blocked randomization that used the table of random numbers from www.randomization.com.

Settings and conduct

In the Akbar Children's Hospital of Mashhad, children aged 2-18 years admitted to PICU will be examined in terms of formula tolerance, blood factors and clinical symptoms in two groups. In the control group, enteral feeding with standard commercial formulas and in the intervention group, handmade enteral nutrition with a specific formulation approved by the ethics committee is given to the patients. The study is single blind, and the analysts in this study are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Children from 2 -18 years old 2. Hospitalization in the pediatric intensive care unit of Akbar Hospital 3. stable hemodynamic conditions 4. Tolerance of bolus feeding 5. The informed consent form must be signed by the parents 6. Having a feeding tube above 12 French Exclusion criteria: 1. Suffering from liver failure 2. Suffering from kidney failure 3. Suffering from metabolic diseases 4. Being allergic to one of the formula ingredients

Intervention groups

In the intervention group, homemade formula with a specific formulation is given, and the control group is given Resource Junior formula.

Main outcome variables

Amount of receiving formulas, symptoms of intolerance including gastric residual volume, diarrhea, constipation,

vomiting, abdominal distention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221219056868N1**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name

Fatemeh Javdan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 2893

Email address

javdanf991@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-19, 1402/02/29

Expected recruitment end date

2023-10-21, 1402/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study The Effect of Enteral Nutrition with Home-made Formula Compared with Commercial Formulas on Tolerance, Blood Factors and Clinical Symptoms in Children Aged 2-18 Years Admitted to PICU

Public title

Study The Effect of Home-made Formulas in Children Admitted to the Intensive Care Unit

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Parents' willingness to cooperate and sign the informed consent form ages 2-18 years hospitalization and Admitted to the PICU stable condition of the person having a NG-Tube above 12 French patients must be able to tolerate Bolus feeding

Exclusion criteria:

Liver failure Renal failure Metabolic diseases include glutaric aciduria type 1 and 2, ketoacidic aciduria, isovaleric acidemia, fatty acid oxidation disorder, fructose metabolism disorder, glycogen storage disease, Pku, tyrosinemia, urea cycle disorders, homocystinuria, propionic acidemia, and methylmalonic acidemia Allergy to one of the formula ingredients

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual-based block randomization will be used in this study. The random sequence will be generated using the website www.sealedenvelope.com and based on blocks of four locations. This step is done by the methodologist of the project and then in order to maintain the concealment of the allocation, the said sequence will be delivered to the researcher in sealed, opaque and numbered envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The designed study is one-sided blind, in which the data analysts are blinded. In this way, the analyst did not inform the information belongs to which group (intervention or control).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Study The effect of enteral nutrition with home-made formula compared with commercial formulas on to

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Faculty of Medicine, Ferdowsi University Campus, East Gate, Azadi Square, Mashhad, Razavi Khorasan

City

mashhad

Province

Razavi Khorasan

Postal code

91379-13131

Approval date

2022-12-25, 1401/10/04

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.546

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

Enteral nutrition with homemade formula

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

tolerance of enteral nutrition (gastric residual volume, diarrhea, constipation, vomiting, abdominal distention)

Timepoint

Daily

Method of measurement

Standard 60 cc gavage syringe for aspiration of digestive contents

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

Weight

Timepoint

The beginning and end of the intervention

Method of measurement

Weighing with a digital scale with high accuracy

2

Description

Subjective Global Nutrition Assessment questionnaire

Timepoint

The beginning and end of the intervention

Method of measurement

Subjective Global Nutrition Assessment questionnaire

3

Description

The amount of formula received within 24 hours

Timepoint

Daily

Method of measurement

The amount of the patient received

4

Description

heel to head

Timepoint

The beginning and end of the intervention

Method of measurement

Using a standard meter

5

Description

mid arm circumference

Timepoint

The beginning and end of the intervention

Method of measurement

Using a standard meter

6

Description

Number of days in hospital

Timepoint

The end of the intervention

Method of measurement

Number of days of hospitalization

7

Description

complete blood count (CBC)

Timepoint

The beginning and end of the intervention

Method of measurement

Using the XN-350 device based on the electrical bioimpedance method In the central laboratory of Akbar Hospital

8

Description

Urea

Timepoint

The beginning and end of the intervention

Method of measurement

with BT-3500 device and BIOMED kit based on

turbidimetry and colorimetry in the laboratory of Akbar Hospital

9

Description

Creatinine

Timepoint

The beginning and end of the intervention

Method of measurement

with BT-3500 device and PARS kit based on turbidimetry and colorimetry in the laboratory of Akbar Hospital

10

Description

C - Reative Protein

Timepoint

The beginning and end of the intervention

Method of measurement

Using Ritonbio Analyze Sclave based on the creation of specific antibody against CRP by photometric method in the central laboratory of Akbar Hospital

11

Description

Albumin

Timepoint

The beginning and end of the intervention

Method of measurement

with BT-3500 device and PARS kit based on turbidimetry and colorimetry in the laboratory of Akbar Hospital

12

Description

alanine transaminase

Timepoint

The beginning and end of the intervention

Method of measurement

with BT-3500 device and ZIST kit in the central laboratory of Akbar Hospital

13

Description

Aspartate Aminotransferase

Timepoint

The beginning and end of the intervention

Method of measurement

with BT-3500 device and ZIST kit in the central laboratory of Akbar Hospital

14

Description

Sodium

Timepoint

The beginning and end of the intervention

Method of measurement

Measurement of sodium by photometric method in the central laboratory of Akbar Hospital

15

Description

Potassium

Timepoint

The beginning and end of the intervention

Method of measurement

Measurement of sodium by film photometry in the central laboratory of Akbar Hospital

16

Description

Calcium

Timepoint

The beginning and end of the intervention

Method of measurement

with BT-3500 device and BIOMED kit based on turbidimetry and colorimetry in the laboratory of Akbar Hospital

17

Description

Magnesium

Timepoint

The beginning and end of the intervention

Method of measurement

with BT-3500 device and PARS kit based on turbidimetry and colorimetry in the laboratory of Akbar Hospital

18

Description

Phosphorus

Timepoint

The beginning and end of the intervention

Method of measurement

with BT-3500 device and PARS kit based on turbidimetry and colorimetry in the laboratory of Akbar Hospital

Intervention groups

1

Description

Intervention group: First, the daily calorie requirement is determined using Schofield's formula, then according to the individual's needs, homemade formulas with specific formulations include 15 grams of carrots, 15 grams of broccoli, 65 grams of chicken breast, 33 grams of rice flour, 20 grams of bananas, 20 grams of apples, and 9 grams of sugar. 27 grams of powdered milk, 11 grams of olive oil and 285 milligrams of water are given. The intervention lasts 14 days.

Category

Treatment - Other

2

Description

Control group: In the control group, the daily calorie requirement is first determined using the Schofield

formula, then according to the needs of the individual, the commercial formula of Resource Junior is given to the patient for 14 days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar hospital in Mashhad

Full name of responsible person

Dr Mohammad Safarian

Street address

Shahid Fakouri Blvd- Fakouri #94- Mashhad - Khorasan Razavi Province- Iran

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https://akbar.mums.ac.ir/index.php/en/?option=com_rsform&view=rsform&formId=24

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Safarian

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Web page address

<https://medical.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohammad Safarian
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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javdanf991@mums.ac.ir

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In case of need, all data will be provided to the research vice-chancellor of Mashhad Medical Sciences in an unidentifiable manner and in compliance with all ethical standards.

When the data will become available and for how long

After conducting the study and defending the student thesis, the findings of the study will be published in the form of student thesis and valid articles.

To whom data/document is available

All researchers in the field of health are able to use the findings of this study if they obtain written permission from the vice president of research of Mashhad University of Medical Sciences and the supervisor of the project.

Under which criteria data/document could be used

After obtaining permission from the Research Vice-Chancellor of Mashhad University of Medical Sciences and the main executive of the project, in order to conduct further studies in this field, the findings of this

study will be available to the researchers.

From where data/document is obtainable

Vice President of Research of Mashhad University of Medical Sciences, the main implementer of the project (Dr. Mohammad Safarian, Professor of Nutrition).

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

Obtaining a written permission from the Research Vice-Chancellor of Mashhad University of Medical Sciences, then referring to the Faculty of Medicine of Mashhad University of Medical Sciences and obtaining permission from the main executive of the project and the director of the Nutrition Department.

Comments