Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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, ketoadipic 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

Street address
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
heal 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 Provience- Iran
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Province
Razavi Khorasan
Postal code
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Phone
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Email
ak.pr@mums.ac.ir
Web page address
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
Street address
Faculty of Medicine, Ferdowsi University Campus, East Gate, Azadi Square, Mashhad, Razavi Khorasan
City
mashhad
Province
Razavi Khorasan
Postal code
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Phone
+98 51 3800 2000
Fax
+98 51 3882 8560
Email
MDS.Dean@mums.ac.ir
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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Faculty of Medicine, Ferdowsi University Campus, East Gate, Azadi Square, Mashhad, Razavi Khorasan

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+98 51 3882 8560

Email
SafarianM@mums.ac.ir

Person responsible for scientific 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 updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Fateme Javdan

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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

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Email
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