Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of pancratic enzyme replacement therapy on anthropometric criteria in children with failure to thrive : A randomized controlled clinical trial

Protocol summary

Study aim

To determine the therapeutic effect of pancreatic enzymes to increase the growth criteria of children with moderate and severe malnutrition

Design

A randomized controlled clinical trial with parallel group, single blind, phase 3 on 60 children. Randomization was done by SAS software.

Settings and conduct

17 shahrivar childrens' hospital, Rasht

Participants/Inclusion and exclusion criteria

All children aged 2 to 14 years with moderate and severe malnutrition who have a Z-score less than -2 will be included in the study. Patients who have type 3 growth disorder or type 2 growth disorder that hormonal problems have not been ruled out by an endocrinologist, or organic problems such as heart disease, lung disease, malabsorption disorder, exocrine pancreatic insufficiency, steatorrhea, and kidney disease are not included in the study.

Intervention groups

Intervention group: All studied children received routine treatment in the form of daily zinc 0.3 mg/kg body weight unit, maximum 6 mg daily from zinc plus syrup (Eurovital brand) and elemental iron at the age of 2 -5 years 25 mg weekly and over 5 years 45 mg weekly of ferrous sulfate syrup (Abidi Company) and vitamin D 600 daily units of Vitamin D Ultra 1000 drops from the VitaBiotix brand, in addition to a specific nutritional program, which is in the form of a diet with increasing 300 to 500 calories are prescribed to the patients according to the condition of the patient. These children are treated for a two-month period with pancreatic enzymes (PERT) [Creon capsule (Abbott company) 25,000, which contains amylase 18,000, protease 1,000, and lipase 25,000] at the rate of 1,000 u/kg during 3 main meals (breakfast, lunch, dinner). Control group: All studied children undergo routine treatment the same as the intervention group.

Main outcome variables

Weight Gain: Weight is measured by a Seca scale (Germany) at the beginning and 2 months after.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230313057703N1**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **prospective**

Last update: **2023-06-18, 1402/03/28**
Update count: **0**

Registration date

2023-06-18, 1402/03/28

Registrant information

Name

Shohreh Maleknejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of pancratic enzyme replacement therapy on anthropometric criteria in children with failure to thrive : A randomized controlled clinical trial

Public title
The effect of pancratic enzyme replacement therapy on anthropometric criteria in children with failure to thrive
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
2-14-year-old patients with failure to thrive whose Z-SCORE weight is below -2.
Exclusion criteria:
type 3 failure to thrive Type 2 growth disorder that hormonal problems have not been ruled out by an endocrinologist. cardiovascular diseases pulmonary diseases malabsorption Pancreatic exocrine insufficiency steatorrhea renal diseases
Age
From **2 years** old to **14 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize the treatment between the groups, the permutation randomization block method with size 4 will be used. Taking into account the time of the entry of people into the study and considering A (intervention group) and B (placebo group), a part of the random allocation will be in the following order: Randomization was done with SAS software version 9.
Blinding (investigator's opinion)
Single blinded
Blinding description
Considering that the researcher and the patient may be aware of the type of intervention due to the difference in the prescribed drugs of the two groups, only the analyst will be blinded to the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Guilan University of Medical Sciences
Street address
siadati
City
Rasht
Province
Guilan
Postal code
4167811969
Approval date
2023-05-17, 1402/02/27
Ethics committee reference number
IR.GUMS.REC.1402.087

Health conditions studied

1

Description of health condition studied
Failure To Thrive in Child
ICD-10 code
R62.8
ICD-10 code description
Other lack of expected normal physiological development

Primary outcomes

1

Description
weight gain
Timepoint
At the beginning and 2 months after
Method of measurement
Weight is measured by a Seca scale (Germany) [this scale is calibrated every day], then the patients will be treated for 2 months and re-examined with the same scale.

Secondary outcomes

1

Description
Height raise
Timepoint
at the beginning and 2 months after
Method of measurement
Height is measured by a tape measure from Seka (Germany), standing without shoes and attached to the wall at the beginning and 2 months after treatment.

2

Description
BMI raise
Timepoint
at the beginning and 2 months after
Method of measurement
BMI is calculated by dividing weight in kilograms by height in square meters.

3

Description
z score raise
Timepoint
at the beginning and 2 months after
Method of measurement
By putting weight, height, and BMI in the Medscape calculator software, the Z SCORE number is reported.

Intervention groups

1

Description
Intervention group: The intervention group received the following routine treatment: All the studied children received routine treatment in the form of daily zinc 0.3 mg/kg body weight unit, maximum 6 mg daily from zinc plus syrup (Eurovital brand) and elemental iron at the age of 2 -5 years 25 mg weekly and over 5 years 45 mg weekly of ferrous sulfate syrup (Abidi Company) and vitamin D 600 daily units of Vitamin D Ultra 1000 drops from the VitaBiotix brand, in addition to a specific nutritional program, which is in the form of a diet with increasing 300 to 500 calories are prescribed to the patients according to the condition of the patient under the supervision of a nutritionist. During the period of intervention, the patients are under the supervision of a gastroenterologist for 2 months, and the parents are asked to change their eating style. In addition, these people are treated for a two-month period with pancreatic enzymes (PERT) [Creon capsule (Abbott company) 25,000, which contains amylase 18,000, protease 1,000, and lipase 25,000] at the rate of 1,000 u/kg during 3 main meals (breakfast, lunch, dinner).
Category
Treatment - Drugs

2

Description
Control group: All studied children under routine treatment in the form of daily zinc 0.3 mg per kg of body weight unit maximum 6 mg daily from zinc plus syrup (Eurovital brand) and elemental iron at the ages of 2-5 years 25 mg weekly and over 5 years of age, 45 mg weekly of ferrous sulfate syrup (Abidi company) and vitamin D 600 daily units of Vitamin D Ultra 1000 drops from the VitaBiotix brand, in addition to a specific nutritional program, which is in the form of a diet with an increase of 300 to 500 calories according to the conditions. It was prescribed to the patients under the supervision of a nutritionist, and during the intervention period, the patients are followed up by a nutritionist for a period of 2 months, and they are under the supervision of a gastroenterology specialist, and parents are asked not to make any changes in the children's eating style.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
17 shahrivar hospital
Full name of responsible person
shohreh maleknejad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Shohreh Maleknejad
Position
Associate professor
Latest degree
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Subspecialist
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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
regarding the ethical issues
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
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable