# 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)

**Phone**

+98 13 3336 9002

**Email address**

maleknejadshohreh@yahoo.com


**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
**Street address**
siadati
**City**
rasht
**Province**
Guilan
**Postal code**
4167811969
**Phone**
+98 13 3336 9019
**Email**
maleknejadshohreh@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Rasht University of Medical Sciences
**Full name of responsible person**
mohammadreza naghipour
**Street address**
siadati
**City**
rasht
**Province**
Guilan
**Postal code**
4167811969
**Phone**
+98 13 3333 5820
**Email**
research@gums.ac.ir
**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**
Subspecialist
**Other areas of specialty/work**
Pediatrics
**Street address**
Namjoo street
**City**
Rasht
**Province**
Guilan
**Postal code**
4167811969
**Phone**
+98 13 3336 9002
**Fax**
**Email**
maleknejadshohreh@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Rasht University of Medical Sciences
**Full name of responsible person**
Shohreh Maleknejad
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
**Street address**
Namjoo street
**City**
Rasht
**Province**
Guilan
**Postal code**
4167811969
**Phone**
+98 13 3336 9002
**Fax**
**Email**
maleknejadshohreh@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Rasht University of Medical Sciences
**Full name of responsible person**
Shohreh Maleknejad
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
**Street address**
Namjoo street
**City**
Rasht
**Province**
Guilan
**Postal code**
4167811969
**Phone**
+98 13 3336 9002
**Fax**
**Email**
maleknejadshohreh@yahoo.com

## 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