

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation the effectiveness of a food supplement based on Traditional Persian Medicine to improve children Failure to Thrive

Protocol summary

Summary

The aim of this study is to evaluate the effectiveness of a food supplement based on Traditional Persian Medicine to improve failure to thrive of children with moderate wasting. The study is a single blind randomized clinical trial. A total of 70 children 12-18 months old with moderate wasting (weight for height Z score less than -2 and equal or greater than -3) will be enrolled. Those who have a history of congenital anomalies or any underlying diseases, will be excluded. At first, children are referred to an associated professor of pediatric gastroenterology, through health centers of Sabzevar city to visit and rule out of any other disease. Then, children randomly will be allocated into two groups. The control group will receive ferrous sulfate as 15 drops per day, Zincovit B as 5 milliliter per day in addition nutritional education. The intervention group will use the food supplement in addition to those mentioned. The intervention period will be last for 12 weeks in both groups. The main intervention of this study is a powder shape food supplement, serving as 70 grams in two meals a day in the form of porridge. Children's weight and height will be measured every two weeks by a digital scale and a length board. The weight for height index will be calculated by using WHO Anthro Software version 3.2-2011. At the end of the study, mean chang in weight for height Z score will be compared before and after intervention between groups.

General information

Acronym

In this study does not apply

IRCT registration information

IRCT registration number: **IRCT2015112125168N1**

Registration date: **2016-01-22, 1394/11/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name

Roghayeh Javan

Name of organization / entity

Mashhad University of Medical Sciences Faculty of Iranian Traditional Medicine and Complementary

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2188

Email address

javanr911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Mashhad University of Medical Sciences

Expected recruitment start date

2016-01-05, 1394/10/15

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of a food supplement based on Traditional Persian Medicine to improve children Failure to Thrive

Public title

Effects of Food supplement on Failure to Thrive

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children with failure to thrive; moderate wasting; having weight for length Z score less than -2 and equal or greater than -3 according to WHO criteria; without underlying disease; age range between 12-18 months Exclusion criteria: any history of acute or chronic disease; history of congenital anomalies or genetic diseases; history of allergy and asthma ; lack of consent of parent to continue the project; having weight for length Z score less than -3; child's absence at two consecutive follow-up time

Age

From **1 year** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences
Administration, Building Qureshi, Daneshgah Ave.

City

Mashhad

Postal code

91388-13944

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

IR.MUMS.REC.1394.528

Health conditions studied

1

Description of health condition studied

failure to thrive

ICD-10 code

R62.8

ICD-10 code description

Lack of Other lack of expected normal physiological development

Primary outcomes

1

Description

Weight

Timepoint

Before intervention, once every two weeks after intervention

Method of measurement

in grams, by digital scale

2

Description

Height

Timepoint

Before intervention, once every two weeks after intervention

Method of measurement

in centimeter, by length board

3

Description

weight for length Index

Timepoint

Before intervention, once every two weeks after intervention

Method of measurement

Zscore weight for length, by WHO Anthro Software version 3.2-2011

Secondary outcomes

1

Description

Side effects

Timepoint

once every two weeks

Method of measurement

Daily questionnaire filled by mothers at home

Intervention groups

1

Description

control group: ferrous sulfate drop as 15 drop per day, Zincovit B syrup as 5 milliliter per day in addition to nutritional education. Nutritional education will be given

to the mother about feeding and increase the quantity and quality meals, at the beginning of the study in a session. This session lasts about 30 minutes.

Category

Treatment - Drugs

2**Description**

Intervention group: ferrous sulfate drop as 15 drop per day, Zincovit B syrup as 5 milliliter per day, nutritional education to mothers and food supplement. Nutritional education will be given to the mothers about feeding and increase the quantity and quality meals at the beginning of the study. The session lasts 30 minutes. The powder form food supplement will be prepared in packages of 1000 grams, given to the mothers with a recipe once every two weeks. 70 grams of this food supplement is served in two meals a day, as porridge. The intervention period lasts for 12 weeks.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Speciality Clinic affiliated to Sabzevar University Medical Sciences

Full name of responsible person

Roghayeh Javan

Street address

Speciality Clinic affiliated to Sabzevar University Medical Sciences, Opposite the Keshavarzi Bank, Seyed Jamaloddin Asad Abadi Ave.

City

Sabzevar

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences, Building Qureshi, Daneshgah Ave.

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Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Full name of responsible person

Roghayeh Javan

Position

PhD student of Iranian Traditional Medicine and Complementary

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Assistant Professor

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Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

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City**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty