Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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 between12-18 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 lenght Index
Timepoint
Before intervention, once every two weeks after intervention
Method of measurement
Zscore weight for lenght, 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.

City

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

Other areas of specialty/work

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Faculty of Iranian Traditional Medicine and Complementary, Opposite the Mehran sports hall, East Razi Ave.

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Person responsible for scientific inquiries

Contact

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

Full name of responsible person

Mahdi Yousefi

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
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Web page address

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