

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The comparison between high calorie, high fat diets with different glycemic indexes effect on some biomarkers related to diabetes and inflammatory factors and cytokines in children and adolescents with cystic fibrosis.

Protocol summary

Summary

The aim of the present study is to compare the effectiveness of high-calorie, high-fat diets with different glycemic index, on some indicators related to diabetes and inflammatory factors and cytokines in children and adolescents with cystic fibrosis. This study is a randomized controlled trial. Populations are children and adolescents with cystic fibrosis who will come to cystic fibrosis clinic in Children Medical Center. After that cystic fibrosis in patients was approved by pulmonologists, patients will be referred to nutrition team in order to get proper diet. 42 Subjects will be randomly divided into two groups. For each patient anthropometric measurement and general characteristics will be assessed and 10 cc fasting blood sample will be taken at the baseline and end of the study. 24-h food record questionnaires will be completed every four week. Inclusion criteria include children and adolescents aged 2-18; children and adolescents who affected disease is confirmed by genetic or sweat test; willingness to cooperate the study. Exclusion criteria includes unwilling to cooperate and continue the study; inability to pursue each types of the diet; urgent need of hospitalization during trial; urgent need of operation during trial. Subjects will randomly receive either type of diets for 12 weeks. In last visit after three months from the beginning of the intervention, 10 cc of blood for biochemical assessment will be taken and height, weight and BMI of the patients after three months of intervention will be recorded in general information form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102325267N5**

Registration date: **2017-11-13, 1396/08/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-13, 1396/08/22

Registrant information

Name

Maryam Mahmoudi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between high calorie, high fat diets with different glycemic indexes effect on some biomarkers related to diabetes and inflammatory factors and cytokines in children and adolescents with cystic fibrosis.

Public title

Comparison between two different diets in children and adolescents with cystic fibrosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: children and adolescents aged 2-18; children and adolescents who affected disease is confirmed by genetic or sweat test; willingness to cooperate Exclusion criteria: unwilling to cooperate and continue; inability to pursue each types of the diet; urgent need of hospitalization during trial; urgent need of operation during trial

Age

From **2 years** old to **19 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, conjunction of Keshavarz Blvd and Qods Street, Tehran, Iran

City

Tehran

Postal code**Approval date**

2017-08-14, 1396/05/23

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3171

Health conditions studied**1****Description of health condition studied**

cystic fibrosis

ICD-10 code

E84

ICD-10 code description

cystic fibrosis

Primary outcomes**1****Description**

fasting blood glucose

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

2**Description**

HDL cholestrol

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

measurement of variables blood level biochemically

3**Description**

LDL cholestrol

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

measurement of variables blood level biochemically

4**Description**

Total cholestrol

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

measurement of variables blood level biochemically

5**Description**

HbA1c

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

6

Description

INF gamma

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

7

Description

IL17-A

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

8

Description

IL-10

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

9

Description

IL-6

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Height

Timepoint

begining of the trial and three months

Method of measurement

meter

2

Description

weight

Timepoint

begining of the trial and three months

Method of measurement

Scale

Intervention groups

1

Description

Intervention group: following high fat, high calorie diet with low glyceic index for three months

Category

Prevention

2

Description

control group: following high fat, high calorie diet, with glyceic index higher than 55 for three months

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Zahra Gorji

Street address

No. 44, Hojatdoost Alley, Naderi St, Keshavarz blv, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Mrs Hassan Pour

Street address

No. 44, Hojatdoost Alley, Naderi St, Keshavarz blv, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Mahmoudi

Position

PhD of Nutrition/Associate Professor of School of Nutritional Sciences and Dietetics in Tehran Unive

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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zahra Gorji

Position

PhD Student in Nutrition Sciences

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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