

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Effect of synbiotic supplementation in comparison with placebo on anthropometric indeices, quality of life and clinical outcome in children with cystic fibrosis.

Protocol summary

Summary

The aim of the present study is determining the effect of Synbiotic supplementation on anthropocentric indices, quality of life, frequency of pulmonary exacerbation, frequency of hospitalization and antibiotic therapy in children with cystic fibrosis. This study is a clinical trial. The study population will consist of 40 children with cystic fibrosis. The inclusion are children with cystic fibrosis aged between 5-12 years. The exclusion criteria are having other disease including diabetes, cirrhosis, hypo-Albominemia, ventilator dependent respiratory failure. After measuring weight and height, BMI will be calculated and after then, the amount of antibiotic consumption, frequency of pulmonary exacerbation, frequency of hospitalization are recorded and gastrointestinal discomfort (diarrhea) and quality of life of children are evaluated and after getting the informed consent, the children will randomly assign to intervention or placebo group according to their age and sex. The patients in intervention group will receive 2 synbiotic capsules daily 2 hours after antibiotic treatment and the patients in placebo group will receive 2 placebo daily for 6 month. The primary outcomes are monthly measuring of weight, height, BMI, frequency of hospitalization and pulmonary exacerbation, bimonthly evaluation of oral or IV antibiotic receiving for 6 month, monthly assessment of diarrhea frequency and quality of life using pedsQL 4.0. For total antioxidant assessment, RANDOX kit will be used and for MDA assessment spectrophotometry method will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011732004N1**
Registration date: **2017-02-14, 1395/11/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-14, 1395/11/26

Registrant information

Name

Zeinab Nikniaz

Name of organization / entity

Liver and gastrointestinal disease research center,
Tabriz University of medical sciences-Tabriz_Ir

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 7473

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nikniazz@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Pediatrics health research center

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2019-04-01, 1398/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of synbiotic supplementation in comparison with placebo on anthropometric indeices, quality of life and

clinical outcome in children with cystic fibrosis.

Public title

Effect of synbiotic in cystic fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children with cystic fibrosis; aged between 5-12 years exclusion criteria: having other disease including diabetes; cirrhosis; hypo-albuminemia; ventilator dependent respiratory failure

Age

From **5 years** old to **12 years** old

Gender

Male

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

a

Secondary trial Id

a

Registration date

2017-11-22, 1396/09/01

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of medical sciences

Street address

Daneshgah St. Tabriz University of medical sciences

City

Tabriz

Postal code

Approval date

2016-10-24, 1395/08/03

Ethics committee reference number

IR.TBZMED.REC.1395.919

Health conditions studied

1

Description of health condition studied

Cystic fibrosis

ICD-10 code

E84

ICD-10 code description

E84.0 Cystic fibrosis with pulmonary manifestations

Primary outcomes

1

Description

Anthropocentric measures

Timepoint

before supplementation and every month after supplementation for 6 month

Method of measurement

scale and stadiomete

2

Description

Diarehea

Timepoint

Before supplementation and every month after supplementation for 6 month

Method of measurement

Questionnaire

3

Description

Quality of life

Timepoint

before supplementation and every month after supplementation for 6 month

Method of measurement

Questionnaire

4

Description

antibiotic treatment (oral and IV therapy)

Timepoint

before supplementation and 2, 4 and 6 month after supplementattion

Method of measurement

Questionnaire

5

Description

hospitalization

Timepoint

before supplementation and every month after supplementation for 6 month

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Serum total antioxidant

Timepoint

before and after six month of supplementation

Method of measurement

commercial kit

Intervention groups

1

Description

intervention: 2 synbiotic capsule per day fami lact capsuls from Zist Takhmir factory capsuls include: 10 9 bacteria namely Lactobacillus casei, Lactobacillus Ramnosis, Lactobacillus bolgaricus, streptococcus thermophilus, bifidobacterium Langom and fructooligosaccharide (FOS) prebiotic

Category

Treatment - Drugs

2

Description

2 placebo capsules/day including corn starch

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric educational and treatment center

Full name of responsible person

Dr Nemat Bilan

Street address

Sheshgelan, Tabriz pediatrics hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pediatric health research center

Full name of responsible person

Dr Mohammad barzgar

Street address

Sheshgelan, Tabriz pediatric hospital

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pediatric health research center

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Dr Rashidi

Street address

Tabriz University of medical sciences, Daneshgah St. Golgasht Ave. Tabriz-Iran

City

Tabriz

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 of Tabriz University of Medical Sciences

Proportion provided by this source

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

Liver and gastrointestinal disease research center

Full name of responsible person

Dr zeinab Niknaiz

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz Children Hospital
Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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medicine student
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Tabriz University of medical sciences, Medicine faculty, Daneshgha St, Tabriz_Iran
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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