

# 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

###### Email address

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

Sheshgela, 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

Sheshgela, 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

#### Street address

Imam Reza hospital, Tabriz-Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz Children Hospital  
**Full name of responsible person**  
Dr Nemat Bilan  
**Position**  
Proffessor  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
medicineschool, Tabriz University of medical sciences  
**Full name of responsible person**  
Dr Marefat  
**Position**  
medicine student  
**Other areas of specialty/work**  
**Street address**  
Tabriz University of medical sciences, Medicine  
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**Email**  
**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*