

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of curcumin supplementation on anthropometric measurements, quality of life, frequencies of hospitalization, lung infection and antibiotic therapies in children with cystic fibrosis

Protocol summary

Summary

In this randomized clinical trial, 40 children with cystic fibrosis will be recruited. Inclusion criteria are children with cystic fibrosis 5-18 years old. Exclusion criteria include diabetes, cirrhosis, and hypoalbuminemia, severe respiratory failure dependent to oxygen therapy, hypoalbuminemia, intolerance of curcumin supplementation. On the basis of age and gender, patients are randomly assigned into Curcumin group, receiving 2 nano curcumin capsules and 3 capsules 80 mg children <10 years and >10 years respectively or the placebo group receiving placebo capsules for 6 months. Primary outcomes are Pulmonary infection, duration of hospitalization, Oral or IV antibiotics administration. Secondary outcomes are anthropometric measurements, quality of life and gastrointestinal symptoms of children with cystic fibrosis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022826798N1**

Registration date: **2017-08-26, 1396/06/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-26, 1396/06/04

Registrant information

Name

Elnaz Faramarzi

Name of organization / entity

liver and Gastrointestinal Research Center, Tabriz University Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

Email address

faramarzie@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

liver and Gastrointestinal diseases research center, tabriz university of medical sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of curcumin supplementation on anthropometric measurements, quality of life, frequencies of hospitalization, lung infection and antibiotic therapies in children with cystic fibrosis

Public title

Effects of curcumin in children with cystic fibrosis

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: children with cystic fibrosis (age 5-18 year) exclusion criteria: history of diabetes; cirrhosis; hypoalbuminemia; severe respiratory failure dependent to oxygen therapy; intolerance of curcumin supplementation

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

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)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

simple randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comitte of Tabriz University of Medical Sciences

Street address

3rd floore, The Vice Chancellor for Research .Central building no2, Tabriz University of Medical Sciences, Golghasht street, Tabriz

City

Tabriz

Postal code

Approval date

2016-04-11, 1395/01/23

Ethics committee reference number

IR.TBZMED.REC.1395.324

Health conditions studied

1

Description of health condition studied

cystic fibrosis

ICD-10 code

J40-J47

ICD-10 code description

Cystic fibrosis, unspecified

Primary outcomes

1

Description

Pulmonary infection

Timepoint

before and after intervention

Method of measurement

questionnaire

2

Description

duration of hospitalization

Timepoint

before and after intervention

Method of measurement

questionnaire

3

Description

oral or Iv antibiotics administration

Timepoint

before and after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

height

Timepoint

before and after intervention

Method of measurement

mounted tape

2

Description

weight

Timepoint

before and after intervention

Method of measurement

Seca scale

3

Description

quality of life

Timepoint

before and after intervention

Method of measurement

Pedsq14 questionnaire

4

Description

body mass index

Timepoint

before and after intervention

Method of measurement

weight (kg)/height (m)²

5

Description

gastrointestinal disease symptoms

Timepoint

before and after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Patients in Curcumin group aged ≤10 year will receive 2 nano curcumin capsules and children with age >10 year will receive 3 nano curcumin capsules for 6 months.

Category

Other

2

Description

Patients in placebo group aged 10 or >10 year will receive 2 nano curcumin capsules and children with >10 year will receive placebo capsules for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Cure and Health hospital

Full name of responsible person

Ziba sameni

Street address

sheshghalan street, Children Cure and Health hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

liver and gastrointestinal diseases research center,
Tabriz University of medical sciences

Full name of responsible person

Dr.rafie

Street address

first floor, Liver and Gastrointestinal Diseases
Research Center, Imam Reza Hospital, Golghasht
Street , Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

liver and gastrointestinal diseases research center,
Tabriz 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

ChildrenCure and Health Hospital

Full name of responsible person

Ziba Sameni

Position

Pediatric special course student

Other areas of specialty/work

Street address

Children Cure and Health Hospital

City

Tabriz

Postal code

Phone

+98 41 3336 7473

Fax

Email

zibasameni@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Liver and Gastrointestinal Research center

Full name of responsible person

Elnaz Faramarzi

Position

PhD of Nutrition

Other areas of specialty/work

Street address

Imam Reza hospital

City

Tabrzi

Postal code

Phone

+98 41 3336 7473

Fax

Email

elnazfaramarzi849@gmail.com,

faramarzie@tbzmed.ac.ir
Web page address

Email
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Children Cure and Health Hospital
Full name of responsible person
Ziba Sameni
Position
Pediatric special course student
Other areas of specialty/work
Street address
City
Postal code
Phone
+98 41 3336 7473
Fax

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