

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effects of curcumin as a Nutritional Strategy on Clinical and Inflammatory Factors in Children with Cystic Fibrosis

Protocol summary

Study aim

The present study aimed to evaluate the effects of nano-curcumin on CF patients in order to achieve the intrinsic and extrinsic effects of curcumin on the inflammatory process in these patients.

Design

This was a double-blind, randomized, placebo-controlled clinical trial.

Settings and conduct

Akbar Children's Hospital in Mashhad, Iran.

Participants/Inclusion and exclusion criteria

Inclusion Criteria The inclusion criteria of the study were as follows: 1) one or more typical phenotypic features of CF and a minimum of an elevated sweat chloride concentration on two/more occasions or two mutations known to cause CF on separate alleles; 2) age of 5-18 years; 3) pulmonary and gastrointestinal involvement; 4) ability to perform spirometry maneuvers and the minimum FEV1 of $\geq 30\%$ compared to the same age, gender, and height in the normal population; 5) the percentage of oxygen saturation based on pulse oximetry of $\geq 90\%$ at room temperature; 6) no cardiovascular, hepatic, and renal failure; 7) absence of celiac disease and rheumatoid arthritis; 8) no acute pulmonary exacerbation requiring hospitalization within the past four weeks; 9) absence of acute respiratory tract infection; 10) informed consent for participation.

Exclusion Criteria The exclusion criteria of the study were the lack of adherence to the drug regimen and presence of drug tolerance.

Intervention groups

The study population consisted of the patients with known CF referring to the Cystic Fibrosis Clinic at Akbar Children's Hospital.

Main outcome variables

Evaluation of inflammation at three levels: 1) systemic by assessing IL-8 as an inflammatory agent, IL-10 as an anti-inflammatory agent, and hsCRP level in the blood samples; 2) pulmonary with the neutrophil count, and

bacterial/viral culture on the nasopharyngeal swab; 3) gastrointestinal with the calprotectin level in the fecal samples.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048018N1**

Registration date: **2020-07-10, 1399/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-10, 1399/04/20**

Update count: **0**

Registration date

2020-07-10, 1399/04/20

Registrant information

Name

Saeedeh Talebi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effects of curcumin as a Nutritional Strategy on Clinical and Inflammatory Factors in Children with Cystic Fibrosis

Public title
Evaluation of using curcumin as a nutritional strategy on clinical finding and inflammatory markers in children with cystic fibrosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
One or more typical phenotypic features of CF and a minimum of an elevated sweat chloride concentration on two/more occasions or two mutations known to cause CF on separate alleles Age of 5-18 years Pulmonary and gastrointestinal involvement Ability to perform spirometry maneuvers and the minimum FEV1 of $\geq 30\%$ compared to the same age, gender, and height in the normal population The percentage of oxygen saturation based on pulse oximetry of $\geq 90\%$ at room temperature No cardiovascular, hepatic, and renal failure Absence of celiac disease and rheumatoid arthritis No acute pulmonary exacerbation requiring hospitalization within the past four weeks Absence of acute respiratory tract infection Informed consent for participation
Exclusion criteria:
The lack of adherence to the drug regimen Presence of drug intolerance

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

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **30**
30

Randomization (investigator's opinion)
Randomized

Randomization description
All known cystic fibrosis patients referred to the clinic were included in the study based on the inclusion criteria. After that, spirometry was down and patients were divided into two groups using FEV1 with 40% cutoff range: Severe lung disease (FEV1 lower than 40%) and Non severe lung disease (FEV1 higher than 40%). (Stratified randomization based on disease severity). Following that, simple random sampling method was used to select the patients from each groups and each stages divided in to two groups of case

and control by using a table of random numbers .

Blinding (investigator's opinion)
Double blinded

Blinding description
The curcumin and placebo glasses were labeled A and B, respectively and made available to the patients through the double-blind design.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics Committee of Research in Mashhad University of Medical Sciences
Street address
Ferdowsi Blvd., Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
02181455618
Approval date
2019-07-06, 1398/04/15
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.144

Health conditions studied

1
Description of health condition studied
Cystic Fibrosis
ICD-10 code
J44
ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1
Description
Inflammation at three levels: Systemic Inflammation, Pulmonary Inflammation, Gastrointestinal Inflammation.
Timepoint
Before and after three months of trial
Method of measurement
1) Systemic inflammation by assessing IL-8 as an inflammatory agent, IL-10 as an anti-inflammatory agent,

and hsCRP level in the blood samples; 2) Pulmonary inflammation with the neutrophil count, and bacterial/viral culture on the nasopharyngeal swab; 3) Gastrointestinal inflammation with the calprotectin level in the fecal samples.

Secondary outcomes

1

Description

Evaluation of pulmonary function

Timepoint

Before and after three months of trial

Method of measurement

Spirometer

2

Description

Quality of life

Timepoint

Before and after three months of trial

Method of measurement

Cystic Fibrosis Questionnaire(CFQ)

Intervention groups

1

Description

Intervention group: Nano-curcumin (Nano Sina Drug Company, Iran) was prepared as nanomicelle in the form of 70 milligrams of drops in 1 cc. To adjust the drug dose for different ages and considering that the maximum acceptable dose based with the most significant impact and minimum side-effects was 80 milligrams, the required amount was obtained for each subject based on the ratio of the body surface area of the patients. The curcumin and placebo glasses were labeled A and B, respectively and made available to the patients through the double-blind design. The duration of the treatment period was three months.

Category

Treatment - Drugs

2

Description

Control group: The placebo was made of polysorbate with the same color and taste. Placebo glasses were labeled A and B, respectively and made available to the patients through the double-blind design. The duration of the treatment period was three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's Hospital

Full name of responsible person

Seyed Ali Jafari

Street address

Namaz Blvd., Zakaria Land., Akbar Children hospital., Mashhad Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Azadi Squar; Ferdowsi University of Mashhad

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences
Full name of responsible person
 Saeedeh Talebi
Position
 Pediatrician, PhD Student of Nutrition
Latest degree
 Specialist
Other areas of specialty/work
 Pediatrics
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared

When the data will become available and for how long

since 1400 years

To whom data/document is available

Academic and scientific institutions

Under which criteria data/document could be used

I haven't decided on that yet

From where data/document is obtainable

Saeedeh Talebi

What processes are involved for a request to access data/document

Send an email to the author responsible for the project

Comments