

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of probiotic effect on growth indicators and quality of life in children with Cystic Fibrosis

Protocol summary

Summary

This study investigated the effect of probiotics on quality of life, growth indicators and also pulmonary exacerbations in children with Cystic Fibrosis. In this study, 37 patients (2-12 years old) were randomly divided into two groups. The children who did not have the ability of probiotic consumption to cause severe disease or their parents were dissatisfied, were excluded from the study. 20 patients of case group took probiotics for 1 month and 17 patients of control group only took routine treatments. Growth indicators such as weight, height, head circumference (HC) and arm circumference (AC) and pulmonary exacerbations obtained at 1st and 3rd month after giving probiotics administration. Quality of life was also determined with using specific questionnaire PedsQL 4.0 at beginning, 3rd and 6th month and was compared with the control group as well as corresponding months of last year.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205219823N1**

Registration date: **2012-07-25, 1391/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-25, 1391/05/04

Registrant information

Name

Rasool Asoodeh Forootagheh

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 985118544643

Email address

asoudehr901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Mashhad University of Medical Sciences

Expected recruitment start date

2010-06-23, 1389/04/02

Expected recruitment end date

2011-12-23, 1390/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of probiotic effect on growth indicators and quality of life in children with Cystic Fibrosis

Public title

Probiotic effect on growth and quality of life in children with Cystic Fibrosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Ages 2 to 12 years old; Cystic Fibrosis disease confirmed by sweat testing, clinical symptoms and common mutations. Exclusion criteria: Patient intolerance to the medication; A lack of parental consent; Inability of probiotic consumption because of severe disease.

Age

From **2 years** old to **12 years** old

Gender

Both

Review records of patients

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 37

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ghorayshi Building, Daneshgah St.

City

Mashhad

Postal code

Approval date

2011-12-23, 1390/10/02

Ethics committee reference number

88660

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

Number of pulmonary exacerbations

Timepoint

One month after the intervention, three months after the intervention

Method of measurement

2

Description

Quality of Life

Timepoint

Before the intervention, three months after the intervention, six months after intervention

Method of measurement

PedsQL 4.0 questionnaire

3

Description

Height

Timepoint

Before the intervention, one month after the intervention, three months after the intervention

Method of measurement

Wall of examination room

4

Description

Weight

Timepoint

Before the intervention, one month after the intervention, three months after the intervention

Method of measurement

Standard scale

5

Description

Head Circumference

Timepoint

Before the intervention, one month after the intervention, three months after the intervention

Method of measurement

Meter

6

Description

Arm Circumference

Timepoint

Before the intervention, one month after the intervention, three months after the intervention

Method of measurement

Meter

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: Protexin, 2 Capsules, daily, 1 Month

Category

Treatment - Drugs

2**Description**

The control group: No action

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Sheykh Hospital

Full name of responsible person

Dr. Elaheh Abbasnezhad Mohamadabad

Street address

Dr. Sheykh Hospital, Taheri St., Tohid Sq.

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor of Research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ramezani, Research Assistant

Street address

Vice Chancellor of Research, Ghorayshi Building, Daneshgah St.

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor of Research, Mashhad 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**

Ghaem Hospital

Full name of responsible person

Dr. Hamidreza Kianifar

Position

Assistant Professor of Mashhad University of Medical Sciences ; Pediatric gastroenterologist

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

Department of Pediatrics, Ghaem Hospital, Beginning of Ahmadabad Blvd.

City

Mashhad

Postal code**Phone**

+98 51 1840 0001

Fax**Email**

kianifarhr@mums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ghaem Hospital

Full name of responsible person

Dr. Hamidreza Kianifar

Position

Pediatric gastroenterologist

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

Department of Pediatrics, Ghaem Hospital, Beginning of Ahmadabad Blvd.

City

Mashhad

Postal code**Phone**

+98 51 1840 0001

Fax**Email**

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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