

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Effect of probiotics on intestinal inflammation in CF patients whit age morthan 4 years base on fecal calportectine a double blind clinical trial

Protocol summary

Summary

The aim of study is evaluation of probiotic effect on gut inflammation in CF patients on the basis of the level of stool calporotecitn. The CF patients with age over 4 years old who are followed in GI clinic of children medical center and have inclusion criteria (age over 4 years old and pancrease insufficiency) are evaluated, the questionnaire are filled, the stool samples are taker and they are maintained in -80 c for redetection of calportiectin level by Elisa test. 25 patients are considered case, and 25, in control group. The case patient are given probiotic powder 1 suchet/ day for 4 weeks and the control patients are given placebo (maltodextrine) 1 suchet / day for 4 weeks. After 4 weeks the new stool samples are examined again for the level of calportectin due Elisa test. The level of <50 μ gr/ gr stool is considered normal and the level of > 100 μ gr/ gr stool is considered due to gut inflammation. The border line level needs further evaluation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201258778N3**

Registration date: **2012-03-12, 1390/12/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-12, 1390/12/22

Registrant information

Name

Farzaneh Motamed

Name of organization / entity

Children Medica ICenter

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 4545

Email address

fmotamed@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

drug and placebo send by producer company without any mony and price for doing test pay by tehran medical univercity

Expected recruitment start date

2012-01-30, 1390/11/10

Expected recruitment end date

2012-04-29, 1391/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotics on intestinal inflammation in CF patients whit age morthan 4 years base on fecal calportectine a double blind clinical trial

Public title

Effect of probiotics on intestinal inflammation in CF patients whit age morthan 4 years

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria; cf patient ; age morethan 4years ; pancrease insufficient ; un use NSAID for 2 weaks ago
exclusion criteria; age before 4 years ; pancrease sufficient ; use NSAID during 2 weaks ago

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 25

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

tehran univercity of medical sience

Street address

boulvar keshavarze ghodse street

City

tehran

Postal code**Approval date**

2020-12-18, 1399/09/28

Ethics committee reference number

90/130/1991

Health conditions studied**1****Description of health condition studied**

cystic fibrosis

ICD-10 code

E 84.1

ICD-10 code description

cystic fibrosis with intestinal manifestation

Primary outcomes**1****Description**

fecal calprotectin

Timepoint

befor of the study and one month later

Method of measurement

measurement of fecal calprotectin

Secondary outcomes

empty

Intervention groups**1****Description**

protexine 2 sachet per day which can mixed with yoghurt

Category

Treatment - Drugs

2**Description**

maltodexerin 2 sachet per day which can mixed in yoghurt

Category

Treatment - Drugs

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

Children Medical Center

Full name of responsible person

Dr Azizollah Yousefi

Street address

Children Medical Center 62 Gharib st 14194 Tehran Iran

City

Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

Ms Alamdar

Street address

Tehran University of Medical Sciences Qods St Bolouvard keshavarz Tehran Iran

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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

Tehran 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

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Person responsible for general inquiries

Contact

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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