

# 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  $\mu$  gr/ gr stool is considered normal and the level of > 100  $\mu$  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

**City**

Tehran

**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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Children Medical Center  
**Full name of responsible person**  
Dr Azizollah Yousefi  
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Pediatric Gastroenterology Flow  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Postal code**  
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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*