

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Clinical trial to investigate the effects of growth hormone on physical growth and clinical status of children with cystic fibrosis

Protocol summary

Summary

(1) Objectives: Our aim in this study was to investigate the effects of growth hormone on physical growth and clinical status of children with cystic fibrosis. (2) Design: This study is a before-after clinical trial which study population are 20 patients with cystic fibrosis diagnosed based on clinical evidence (steatorrhea, nasal polyp, rectum prolapse, history of ileus meconium and relapsing pneumonia), laboratory findings (sweat test more than 60 meq/dl) and genetic evaluation (mutation in CFTR gene) and referred to liver and gastrointestinal wards and clinics. These children will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent. (3) Setting and conduct: After measuring height, weight, body mass index and primary physical exam and filling checklists, blood sample will be taken to measure blood cells, blood glucose and electrolytes, creatinine, liver function tests and albumin. In first 6 months, without administering growth hormone, growth rate, times of lung infections, times of intravenous antibiotic therapy and hospitalization will be measured every two months. After 6 months laboratory exams will be repeated and height and weight will be recorded and spirometry will be performed for all the patients. Growth hormone will be administered with dose of 35 mg/kg/week and will be injected subcutaneous every day. Growth rate and clinical status will be recorded every 2 months for six months. At the end of second six months laboratory exams and spirometry will be performed again. Inclusion criteria are age under 12 years old and height and weight less than third percentile for age and gender. Exclusion criteria are having diabetes, cirrhosis of the liver and hypoalbuminemia and oxygen-related lung disorders. (4) Interventions: Patients will be treated with growth hormone for six months with dose of 35 mg/kg/week and will be injected subcutaneous every day. (5) Main outcome measure: Height, weight, body mass index, times of hospitalizations, times of

intravenous antibiotic therapy which will be recorded every two months after initiating treatment with growth hormone and will be continued for six months.

General information

Acronym

CF

IRCT registration information

IRCT registration number: **IRCT201112275330N3**

Registration date: **2013-06-28, 1392/04/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-28, 1392/04/07

Registrant information

Name

Mandana Rafeey

Name of organization / entity

Liver and gastrointestinal research center, Tabriz
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1331 4135

Email address

rafeem@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to investigate the effects of growth hormone on physical growth and clinical status of children with cystic fibrosis

Public title

Effects of growth hormone on status of children with cystic fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age under 12 years old; height and weight less than third percentile for age and gender; boyd mass index less than tenth percentile for age and gender. Exclusion criteria: Having diabetes (fasting glucose equal or less than 126 mg/dl); history of glucocorticoids in last 6 months; appearance of secondary sex characteristics; Cirrhosis of the liver and hypoalbuminemia; oxygen-related lung disorders.

Age

To **12 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht

Street, Azadi Street, Tabriz

City

Tabriz

Postal code**Approval date**

2012-06-23, 1391/04/03

Ethics committee reference number

543081

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

Cystic fibrosis with pulmonary manifestations

ICD-10 code

E84.0

ICD-10 code description

Cystic fibrosis with pulmonary manifestations

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

Weight

Timepoint

Before administering growth hormone and after administering growth hormone every 2 months for a period of 6 months

Method of measurement

Using scale

2**Description**

Height

Timepoint

Before administering growth hormone and after administering growth hormone every 2 months for a period of 6 months

Method of measurement

Using meter

3**Description**

Times of hospitalization

Timepoint

Before administering growth hormone and after administering growth hormone every 2 months for a period of 6 months

Method of measurement

Questionnaire

4**Description**

Times of lung infection

Timepoint

Before administering growth hormone and after administering growth hormone every 2 months for a

period of 6 months
Method of measurement
Questionnaire

5

Description

Times of intravenous antibiotic therapy

Timepoint

Before administering growth hormone and after administering growth hormone every 2 months for a period of 6 months

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For all the patients, growth hormone will be injected subcutaneous with a dose of 35 mg/kg/week, daily and for six months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Masoud Zamani

Street address

Tabriz Children Hospital, Sheshgelan Street, Farmanfarmayan Street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Seyyed Kazem Shakouri

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht Street, Azadi 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

Vice chancellor for research, 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

Tabriz Children Hospital

Full name of responsible person

Dr. Masoud Zamani

Position

Pediatric diseases resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gastrointestinal Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mandana Refeey

Position

Professor of pediatric gastroenterology

Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz Children Hospital

Full name of responsible person

Dr. Masoud Zamani

Position

Pediatric diseases resident

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

Department of Pediatric diseases, Tabriz Children
Hospital, Sheshgelan Street, Farmanfarmayan Street,
Tabriz

City

Tabriz

Postal code**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