

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the nebulized Mannitol with nebulized Hypertonic saline on pulmonary function in patients with cystic fibrosis

Protocol summary

Study aim

Evaluation of the efficacy of nebulized soluble mannitol and comparison with nebulized 5% hypertonic saline on pulmonary function of children with cystic fibrosis

Design

Two arm parallel group clinical trial with 30 patients

Settings and conduct

Study was performed on 30 children with cystic fibrosis older than 5 years of age who were referred to CF clinic in Mofid Children's Hospital, Tehran, Iran. Patients were divided into two groups including soluble mannitol and 5% hypertonic saline group. Group 1 received nebulized soluble mannitol at 4 cc twice daily and group 2 received nebulized 5% hypertonic saline at 5 cc four times a day. In both groups treatment was performed for two weeks. A baseline and an after two weeks of treatment spirometry was done.

Participants/Inclusion and exclusion criteria

Children with cystic fibrosis older than 5 years who can perform spirometry; Patients less than 5 years.

Intervention groups

Group 1: Receiving nebulized soluble mannitol at 4 cc twice a day. Group 2: Receiving nebulized 5% hypertonic saline at 5 cc four times a day.

Main outcome variables

Pulmonary function based on spirometry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180307038994N1**

Registration date: **2018-04-15, 1397/01/26**

Registration timing: **retrospective**

Last update: **2018-04-15, 1397/01/26**

Update count: **0**

Registration date

2018-04-15, 1397/01/26

Registrant information

Name

Masoud Kiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3234 0755

Email address

m.kiani@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

2016-01-21, 1394/11/01

Actual recruitment end date

2016-06-20, 1395/03/31

Trial completion date

empty

Scientific title

Comparison of the nebulized Mannitol with nebulized Hypertonic saline on pulmonary function in patients with cystic fibrosis

Public title

Effect of Mucolytic in treatment of cystic fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with cystic fibrosis older than 5 years Ability to perform spirometry

Exclusion criteria:
Age less than 5 years

Age
From **5 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Not 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

Ethics committee of Shahid Beheshti University of
Medical Sciences

Street address

Arabi Ave, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2015-10-20, 1394/07/28

Ethics committee reference number

IR.SBMU.SM.REC.1394.62

Health conditions studied

1

Description of health condition studied

Cystic fibrosis

ICD-10 code

E84.0

ICD-10 code description

Cystic fibrosis with pulmonary manifestations

Primary outcomes

1

Description

Pulmonary function based on spirometry

Timepoint

Spirometry at the beginning of study and at the end of
study after two weeks of treatment

Method of measurement

Spirometry device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Receives soluble mannitol at a
concentration of 150 milligram per milliliter at 4 cc twice
a day via nebulizer device.

Category

Treatment - Drugs

2

Description

Intervention group 2: Receives hypertonic saline 5% at 5
cc four times a day via nebulizer device.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's hospital

Full name of responsible person

Masoud Kiani

Street address

Shariati St

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15514- 15468

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoud Kiani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available