Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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 spirometery

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

City
Tehran

Province
Tehran

Postal code
15514- 15468

Phone
+98 21 2222 7029

Email
info-mch@sbmu.ac.ir

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

Street address
Arabi Ave, Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 23871

Email
info@sbmu.ac.ir

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

Street address
Amirkola Children’s hospital, Amirkola, Babol

City
Babol

Province
Mazandaran

Postal code
7411514731

Phone
+98 11 3234 0755

Email
m.kiani@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Masoud Kiani

Position
Assistant professor

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Person responsible for updating data

Contact

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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