

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the effectiveness of 7% plus hypertonic saline in comparison with 7% hypertonic saline in reducing the growth of Pseudomonas aeruginosa in lung of the patient with cystic fibrosis disease.

Protocol summary

Study aim

To determine the effectiveness of inhalation of hypertonic saline 7% plus in comparison with inhalation of hypertonic saline 7% in reducing the growth of P. aeruginosa, in the lungs of patients with cystic fibrosis.

Design

parallel group non-randomised Clinical trial with control .

Settings and conduct

Patients are nonrandomized divided into two groups, the intervention group, hypertonic saline 7% plus inhalation, and the control group, hypertonic saline 7% inhalation, which is used with a jet nebulizer at intervals of every 12 at home for two months. The study is measured before and after drug administration and is then compared between the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients have cystic fibrosis, patients have the ability to excrete sputum, The disease is in a stable condition (not in exacerbation), (FEV1) is above 50%. have pseudomonas in sputum culture. Exclusion criteria: Hyper reactive airway disease, Oxygen saturation less than 94% in room air or with supplemental oxygen, Change in cystic fibrosis drugs during the previous 4 weeks, Untreated reflux.

Intervention groups

The intervention group is treated with hypertonic saline 7% plus inhalation and the control group is treated with hypertonic saline 7% inhaled. hypertonic saline plus contains bicarbonate for diluting of sputum and inhibit P. Aeruginosa growth in sputum. The nebulizer is used twice a day, for 2 months. This drug is Iranian and made by Samen Pharmaceutical Group.

Main outcome variables

Weight, Colony count of p. aeruginosa in sputum culture, Quality of life ,FEV1, FVC, LCI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201017049055N1**

Registration date: **2021-04-23, 1400/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-23, 1400/02/03**

Update count: **0**

Registration date

2021-04-23, 1400/02/03

Registrant information

Name

Fateme Tarighat monfared

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2227 6175

Email address

fateme.tarighat@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of 7% plus hypertonic saline in comparison with 7% hypertonic saline in reducing the growth of Pseudomonas aeruginosa in lung of the patient with cystic fibrosis disease.

Public title

Effect of hypertonic saline 7% plus in treatment of Pseudomonas aeruginosa in the lung of the patient with cystic fibrosis disease.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

positive sputum culture with Pseudomonas aeruginosa
The patient has the ability to excrete sputum
The disease is in a stable condition (not in exacerbation)
Forced expiratory volume (FEV1) is above 50%. have cystic fibrosis disease.

Exclusion criteria:

have hyper reactive airway disease. O2 saturation below 94%, in air room or when treated with oxygen. changes in cystic fibrosis drug over the past 4 weeks. have untreated reflux disease.

Age

From **6 years** old to **13 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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 in Research of Pediatric Medical Center-Tehran University of Medical Sciences.

Street address

No. 62, Pediatric Medical Center, Next to Imam

Khomeini Hospital, Dr. Mohammad Gharib St., End of Keshavarz Blvd., Tehran.

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2020-10-08, 1399/07/17

Ethics committee reference number

IR.TUMS.CHMC.REC.1399.133

Health conditions studied

1

Description of health condition studied

cystic fibrosis

ICD-10 code

E84

ICD-10 code description

Cystic fibrosis

Primary outcomes

1

Description

Number of colony count of pseudomonas aeruginosa.

Timepoint

It is measured before prescribing the drug and then 2 months after prescribing the drug.

Method of measurement

Counting colonies after sputum culture.

2

Description

Weight

Timepoint

It is measured before prescribing the drug and then 2 months after prescribing the drug.

Method of measurement

scale

3

Description

Forced expiratory volume in first second (FEV1)

Timepoint

It is measured before prescribing the drug and then 2 months after prescribing the drug.

Method of measurement

Spirometry

4

Description

LCI (Lung clearance index)

Timepoint

It is measured before prescribing the drug and then 2

months after prescribing the drug.

Method of measurement

Polmonary function test(LCI)

5

Description

Quality of life

Timepoint

It is measured before prescribing the drug and then 2 months after prescribing the drug.

Method of measurement

CFQ-R Questionnaire

6

Description

Forced vital capacity(FVC)

Timepoint

It is measured before prescribing the drug and then 2 months after prescribing the drug.

Method of measurement

Spirometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the usage of hypertonic saline 7% plus inhalation by a nebulizer ,twice a day for 2 months.drug Produced by Samen Pharmaceutical Company of Mashhad.

Category

Treatment - Drugs

2

Description

control group: the usage of hypertonic saline 7% inhalation by a nebulizer ,twice a day for 2 months.drug Produced by Samen Pharmaceutical Company of Mashhad.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's medical center

Full name of responsible person

Fateme Tarighat Monfared

Street address

No. 62, Next to Imam Khomeini Hospital, Dr. Mohammad Gharib St., at the end of Keshavarz Boulevard, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad ali Sahraeian.

Street address

Central Campus of the University of Tehran, Vice Chancellor for Research, 16 Azar St., Enghelab St., Enghelab Square, Tehran

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Tehran

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1417614411

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resaerch@ut.ac.ir

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

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

Tehran University of Medical Sciences

Full name of responsible person

Fateme Tarighat monfared

Position

Polmonary subspecialties assistant

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

No.50 (unit 2), Mahshid Alley ., End of north
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

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Position

Polmonary subspecialties assistant

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

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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

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

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