

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Investigating the effectiveness of 7% plus hypertonic saline compared to 7%hypertonic saline in reducing the growth of Pseudomonas in the lungs of cystic fibrosis patients

Protocol summary

Study aim

Determining the effectiveness of 7% hypertonic saline plus compared to 7% hypertonic saline in reducing the growth of Pseudomonas in the lungs of cystic fibrosis patients

Design

A randomized, double-blind, parallel-group, controlled clinical trial study was conducted on 64 cystic fibrosis patients, using random allocation software for randomization.

Settings and conduct

The location of the study and clinical trial is in the clinic of Akbar Children's Hospital in Mashhad. Patients with cystic fibrosis will be divided into two intervention and control groups. All patients will have their sputum cultured for Pseudomonas aeruginosa colony count and spirometry performed before medication is prescribed. In this study, random assignment has been performed and it is single-blind (assessor). First, the ethical consent form is completed by the children's parents. After filling out the questionnaire, the child's body mass index and spirometry results are calculated and entered into the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Presence of cystic fibrosis, ability to expectorate sputum, stable disease (not in exacerbation), forced expiratory volume in one second greater than 50%. Exclusion criteria: Hyperreactive pulmonary disease, oxygen saturation less than 94% on room air or with supplemental oxygen, use of intravenous antibiotics within the previous 4 weeks.

Intervention groups

the patients in the intervention group received hypertonic saline 7 % for 3 months, which is produced by Samen company, Mashhad, for 3 months. Patients in the control group receive 4 cc of 7% hypertonic saline nebulizer which is produced by Samen company,

mashhad, every 12 hours for 3 months.

Main outcome variables

Pseudomonas aeruginosa colony count growth rate in patients' sputum, forced expiratory volume in 1 second, forced vital capacity, body mass index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250217064754N1**

Registration date: **2025-07-08, 1404/04/17**

Registration timing: **retrospective**

Last update: **2025-07-08, 1404/04/17**

Update count: **0**

Registration date

2025-07-08, 1404/04/17

Registrant information

Name

Faeze Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3966 5512

Email address

fasamadi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-05, 1404/03/15

Expected recruitment end date

2025-06-20, 1404/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of 7% plus hypertonic saline compared to 7%hypertonic saline in reducing the growth of Pseudomonas in the lungs of cystic fibrosis patients

Public title

The effect of saline Plus on cystic fibrosis patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Have cystic fibrosis ability to expectorate sputum The patient is in stable condition Pseudomonas sputum culture The forced expiratory volume in the first second is greater than 50%.

Exclusion criteria:

Hyperreactive pulmonary disease Oxygen saturation less than 94% in room air or with supplemental oxygen Use of intravenous antibiotics during the previous four weeks Change in cystic fibrosis medications in the past four weeks

Age

From **6 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block method will be used to generate the sequence of random allocation of individuals to the study groups. The sequence of random allocation of individuals will be done using Random Allocation Software and a block size of 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

1. Blinding of participants - Both types of saline (7% regular and 7% plus) are provided in identical containers (same brand, color, shape, and packaging). - Labels are marked only with random codes (e.g., A or B) and do not indicate the type of drug. - If the drugs have a different taste or smell, a neutral flavoring or color is used so that they are not distinguishable. 2. Blinding of investigators (drug prescribing team) - The research team does not have access to the randomization list (this list is

managed by a pharmacist or a central system outside the team). - The drugs are pre-coded, and the investigator only gives the code (e.g., vial "A") to the patient without knowing the contents. - In the event of adverse events, reports are recorded without specifying the treatment group. 3. Blinding of outcome assessors (data analysis team) - Samples (e.g., sputum cultures) are sent to the laboratory with numerical codes (not A/B). - Assessors do not know which treatment group each sample belongs to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of the Faculty of Medicine, Mashhad University of Medical Sciences

Street address

Central Organization of Mashhad University of Medical Sciences, Knowledge and Health Town,between Shahid Al-Shahidi Square and Shahid Javan Square, , end of Shahid Fakuri Boulevard, , Mashhad city, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2024-11-26, 1403/09/06

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1403.354

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**

Colony growth rate of Pseudomonas aeruginosa in

sputum of patients

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Pseudomonas colony count by throat culture

2**Description**

the Forced Expiratory Volume in 1 second

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Spirometry

3**Description**

the total forced vital capacity

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Spirometry

4**Description**

body mass index

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Meters and scales

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in the intervention group received 4 cc of 7% hypertonic saline plus nebulizer, manufactured by Samen Pharmaceutical Company, every 12 hours for three months.

Category

Prevention

2**Description**

Control Group: Patients in the control group receive 4 cc of 7% hypertonic saline nebulizer, manufactured by Samen Pharmaceutical Company, every 12 hours for three months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akbar Children's Hospital Clinic, Mashhad

Full name of responsible person

Faezeh Samadi

Street address

opposite Kaveh 14, Shahid Kaveh Blvd., Shahid Javan Square, Shahid Fakur Blvd., Mashhad, Razavi Khorasan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad 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

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

Mashhad University of Medical Sciences

Full name of responsible person

Faezeh Samadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Pediatrics

Street address

Akbar Hospital, Shahid Kaveh Blvd.,

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Province

Razavi Khorasan

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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