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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2000

Email

samadif4011@mums.ac.ir

Web page address

https://akbar.mums.ac.ir/index.php/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3882 8883

Email

MDS.Dean@mums.ac.ir

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

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
Street address
Opposite Shahid Kaveh 14, Shahid Kaveh Blvd., Mashhad, Khorasan Razavi, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177897157
Phone
+98 51 3866 5512
Email
fasamadi100@gmail.com

Person responsible for scientific 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
Street address
Akbar Hospital, Shahid Kaveh Blvd.,
City
Mashhad
Province
Razavi Khorasan
Postal code
9919191778
Phone
+98 51 3866 5512
Email
fasamadi100@gmail.com

Person responsible for updating data

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
Street address
Akbar Hospital, Shahid Kaveh Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9919191778
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+98 51 3866 5512
Email
fasamadi100@gmail.com

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