Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Feb 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 salin7% plus in comparison with inhalation of hypertonic salin7% in reducing the growth of P. aeroginosa, 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 salin plus contains bicarbonate for diluting of sputum and inhibit P.Aeroginosa 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
Weigt,Colony count of p.aeroginosa 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
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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 salin7% 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
Nomber of colony count of pseudomonas aeroginosa.

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 volum 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

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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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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
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Specialist
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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