

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the efficacy of nebulized Azithromycin with oral Azithromycin in pulmonary function parameters in CF patients

Protocol summary

Summary

This study conducted to investigate the efficacy of nebulized Azithromycin on pulmonary parameters and SA colonization in sputum and quality of life in CF patients. Recent study is prospective randomized clinical trial. Patients enrolled into the study were 8 to 18 years of age with a documented CF diagnosis (sweat tests more than 60 mEq/L at least two times), and had FEV1 \geq 25% to \leq 75% predicted at baseline, and chronic PA airway infection, not recent (day \geq 28 to screening) administration of inhaled, IV, or oral antipseudomonal antibiotics, not administration of oral Azithromycin at least for two months, not administration of nebulized Amikacin at least for one months. Exclusion criteria included current oral corticosteroid, lung transplantation; recent changes in antimicrobial, bronchodilator, antiinflammatory, or corticosteroid medications, or physiotherapy technique/ schedule; smear-positive sputum for non- Mycobacterium tuberculosis. Sample size is 50. Patients randomly assigned to 28 days of treatment with 70 mg of nebulized AZT or oral AZT every other day (250 mg for weight less than 40 kg and 500 mg for weight more than 40 kg). every group also nebulized aerosolized hypertonic saline solution and salbutamol every day. At treatment end (day 28), spirometry will be performed and sputum will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100930233N1**
Registration date: **2016-10-30, 1395/08/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Andisheh Maneshi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of nebulized Azithromycin with oral Azithromycin in pulmonary function parameters in CF patients

Public title

Effect of nebulized Azithromycin in cystic fibrosis disease

Purpose

Treatment

Inclusion/Exclusion criteria

Patients enrolled into the study were: 8 to 18 years old

with a documented CF diagnosis (sweat tests more than 60 mEq/L at least two times) and had moderate-to-severe lung disease (FEV1 \geq 25% to \leq 75% predicted) and PA airway infection (documented at screening or two times within previous year; including once within the previous 3 months) not recent (ie, day \geq 28 to screening) administration of inhaled, IV, or oral antipseudomonal antibiotics, not administration of oral Azithromycin at least for two months (2 months wash out or has not administered yet or stop taking oral Azithromycin at least for 2 months). Exclusion criteria: current oral corticosteroid, lung transplantation; recent changes in antimicrobial, bronchodilator, antiinflammatory, or corticosteroid medications, or physiotherapy technique/ schedule; smear-positive sputum for non- Mycobacterium tuberculosis.

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

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**

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2015-12-15, 1394/09/24

Ethics committee reference number

IR.TUMS.REC.1394.1403

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**

pseudomonas aeruginosa colony count

Timepoint

screening, Baseline,+28 day Treatment

Method of measurement

sputum Test and culture

2**Description**

FEV1

Timepoint

screening, Baseline,+28 day Treatment

Method of measurement

spirometry

3**Description**

pseudomonas aeruginosa phenotype

Timepoint

Screeninig, Baseline,+28 day Treatment

Method of measurement

sputum Test and culture

4**Description**

pseudomonas aeruginosa resistance pattern

Timepoint

Screeninig, Baseline,+28 day Treatment

Method of measurement

sputum Test and culture

Secondary outcomes

empty

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

In treatment group patients assigned to 28 days of treatment with 70 mg of nebulized AZT

Category

Treatment - Drugs

2

Description

In control group patients assigned to 28 days of treatment with oral AZT every other day (250 mg for weight less than 40 kg and 500 mg for weight more than 40 kg).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center

Full name of responsible person

Street address

Children Medical Center, Dr. Gharib st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masoud Yunesian

Street address

Vice chancellor for research, Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

City

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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

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Children Medical Center

Full name of responsible person

Dr. Andisheh Maneshi

Position

Clinical pharmacist resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty