Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of oral N-acetylcysteine (NAC) comparing to placebo on quality of life and respiratory profile of patients aged 6 to 18 years old with cystic fibrosis having mild to moderate pulmonary involvement

Protocol summary

Study aim

Determining the effectiveness of oral N-acetylcysteine in comparison with placebo in quality of life and respiratory profile of patients aged 6 to 18 years with cystic fibrosis with mild to moderate pulmonary involvement

Design

Pilot clinical trial with quasi-experimental design of single-blind placebo-controlled and add-on therapy (standard treatment is prescribed in both groups and no disease is deprived of its usual treatment).

Settings and conduct

During spring and summer 2021 in cystic fibrosis Clinic of Imam Hossein Children's Hospital in Isfahan. 30 Patients randomly will be divided into two equal groups. The control group will receive standard treatment and placebo. After three months, spirometric indices and quality of life questionnaire in cystic fibrosis will be evaluated in two groups. Patients and physicians will be blind, and the data collector and researcher are aware of the drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chlorine content in sweat test> = 60 milliequivalents per liter or genotype and specific phenotype of cystic fibrosis, patients 6 to 18 years, Forced Expiratory Volume level > = 50% and stable clinical condition in the patient and no acute infection in Respiratory system and non-exacerbation of pulmonary symptoms within 14 days before clinical examination. Non Inclusion criteria: disability to perform and repeat spirometry and use of other drugs outside the common treatment protocol and having underlying diseases

Intervention groups

Both groups received standard treatment for cystic fibrosis, and the intervention group used 200 mg N-acetylcysteine oral tablets every 8 hours for 3 months, and the control group received a placebo.

Main outcome variables

Quality of life by cystic fibrosis Questionnaire -Revised (CFQR); FEV1; FEV1 / FVC; FEF25-75;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090808002306N7**
Registration date: **2021-07-17, 1400/04/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-17, 1400/04/26**
Update count: **0**

Registration date

2021-07-17, 1400/04/26

Registrant information

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Ali Mohammad Sabzghabaee

Name of organization / entity

Isfahan university of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of oral N-acetylcysteine (NAC) comparing to placebo on quality of life and respiratory profile of patients aged 6 to 18 years old with cystic fibrosis having mild to moderate pulmonary involvement

Public title
Oral N-acetylcysteine (NAC) effectiveness in cystic fibrosis (CF)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. The amount of chlorine in the sweat test is greater than or equal to 60 milliequivalents per liter or the presence of genotype containing two diagnostic mutations associated with CF and accompanied by one or more stable clinical symptoms specific to the specific phenotype of cystic fibrosis patients. 2. patients aged range of 6 to 18 years 3. The level of FEV1 or Forced Expiratory Volume is more than 50% 4. Stable clinical condition in the patient and no acute infection in the patient's upper and lower respiratory system 5. Do not aggravate the patient's pulmonary symptoms for 14 days before the patient's clinical examination
Exclusion criteria:
Disability to perform and repeat spirometry test according to American Thoracic Society criteria use of other drugs out of the common treatment protocol that is effective on the disease. Having possible history of underlying cardiovascular, renal, hepatic and biliary tract diseases
Age
From **6 years** old to **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, randomization using the date of birth of patients referred to the outpatient cystic fibrosis treatment clinic of Imam Hossein Pediatric Hospital on Thursdays (Simple Random Sampling) is performed. In this method, using patients' birthdays, all eligible admitted individuals will be divided into two groups of 15 people, case and control. (Birthday of the individual in the case group and birthday of the couple in the control group.) Then the numbers, respectively. Depending on the number or even number of each patient, a treatment regimen with or without NAC is considered.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the pulmonologist and patients are not aware of the type of drug prescribed (main drug or placebo). Drugs with only a small code that only the researcher and data collector (student) is aware of that code.
Placebo
Used
Assignment
Parallel
Other design features
Before entering the study, how to conduct a clinical trial for children / adolescents and their parents will be fully explained and the consent form will be provided to patients both children / adolescents and parents or legal guardians. Individuals in the above method will be randomly divided into two groups of case and control, both groups will receive standard treatment and the intervention group in addition to standard treatment, N acetylcysteine (NAC) oral tablet and the control group will also receive placebo. In order to ensure the correct use of the drug, in addition to the initial training, the pill count method will be used during the follow-up of patients, and if patients have more than 40% difference with the expected number of remaining pills, they will be excluded.from the study. Two hundred mg NAC tablets produced by the pharmaceutical company Mucosulin and placebo with a brand similar in appearance to the main drug are produced by the Isfahan School of Pharmacy and given to the control group. Before receiving the drug, patients in both groups, Spirometry is tested and the indicators mentioned in the targets are recorded. Also, at the beginning of the study, patients' demographic information and details related to the severity of cystic fibrosis (CF) symptoms are recorded in a data collection form. In both case and control groups, receive standard treatment (including saline nebulizers, digestive enzymes, etc.) and to evaluate the effectiveness of N-acetylcysteine in patients with CF in the case group, 600 mg of this drug daily (every eight hours 200 mg tablets) for one to three months. The control group also takes placebo tablets. Then spirometry test is performed on the patients again and the results are compared before and after the intervention in the considered indicators. Spirometry testing is based on the ATS guideline. Before the start of the study, the quality of life of these patients was assessed using the Cystic Fibrosis Questionnaire-Revised (CFQR) and compared between the case and control groups, based on before and after the intervention. Accuracy and reliability of case tests The opinion has been proven in several studies, and during the monitoring of patients during treatment, the possibility of side effects will be reported as observed.۴۵

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfehan University of Medical Sciences
Street address
Hezar jarib street
City
Isfehan
Province
Isfehan
Postal code
8174673461
Approval date
2021-05-08, 1400/02/18
Ethics committee reference number
IR.MUI.MED.REC.1400.218

Health conditions studied

1

Description of health condition studied
Cystic fibrosis
ICD-10 code
E88.8
ICD-10 code description
Other specified metabolic disorders

Primary outcomes

1

Description
Quality of life in children with cystic fibrosis;
Timepoint
At the beginning of the study and 3 months later,
Method of measurement
Cystic fibrosis Questionnaire -Revised (CFQR)

2

Description
FEV1/FVC, proportion of a person's vital capacity that they are able to expire in the first second of forced expiration to the full, forced vital capacity
Timepoint
At the beginning of the study and 3 months later
Method of measurement
By spirometry

3

Description
FEV1, Forced Expiratory Volume in First Second
Timepoint
At the beginning of the study and 3 months later
Method of measurement
By spirometry

4

Description
FEF25-75, Exhale middle airflow
Timepoint
At the beginning of the study and 3 months later
Method of measurement
Spirometry

Secondary outcomes

1

Description
quality of life in cystic fibrosis patients
Timepoint
At the first beginning of the study and 3 months later
Method of measurement
By a questionnaire Cystic Fibrosis Questionnaire -Revised (CFQR)

Intervention groups

1

Description
Intervention group: N acetylcysteine at a dose of 200 mg 3 times a day for 3 months by a pharmaceutical company.
Category
Treatment - Drugs

2

Description
Control group: receiving standard treatment for cystic fibrosis plus placebo with the same shape every 8 hours for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Cystic Fibrosis Clinic of Imam Hossein Pediatric Hospital, Isfahan
Full name of responsible person
Mohsen reisi
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Sponsors / Funding sources

1

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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
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Esfahan University of Medical Sciences
Full name of responsible person
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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

Yes - There is 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

Title and more details about the data/document

No decision is made

When the data will become available and for how long

No decision is made

To whom data/document is available

No decision is made

Under which criteria data/document could be used

No decision is made

From where data/document is obtainable

No decision is made

What processes are involved for a request to access data/document

No decision is made

Comments