

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of zinc supplementation on pulmonary function in adults with cystic fibrosis in Imam Khomeini Hospital in 2023 , Randomize clinical trial

Protocol summary

Study aim

Investigating the effect of zinc supplementation on pulmonary function

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized

Settings and conduct

In the implementation method of this plan, which is done in the form of a clinical trial, all patients referred to the CF clinic are examined. Then, the entry and exit criteria of the patients are entered and randomly divided into 2 groups receiving zinc supplement or placebo with the help of a computerized random number table. As a clinical group, 30 mg zinc tablets are given to patients daily. In the second group of patients, they have previously suffered from cystic fibrosis, which was diagnosed with genetic tests, and in both groups of patients, they did not mention a history of lung disease or cardiovascular disease. During the period of 3 months, regularly in the morning. The patients in the first group are given 30 mg zinc supplement

Participants/Inclusion and exclusion criteria

The first group has a history of cystic fibrosis, which was confirmed by genetic tests that have already been done, and as a clinical group, 30 mg zinc tablets are given to patients daily. In the second group of patients, they have previously suffered from cystic fibrosis, which was diagnosed with genetic tests, and in both groups of patients, they did not mention any history of lung disease or cardiovascular disease.

Intervention groups

During the period of 3 months, the patients in the first group are given 30 mg of zinc supplement regularly in the mornings, and in the second group, a placebo with the same form but without zinc supplement is given 1 daily and regularly during 3 months.

Main outcome variables

Finally, after 3 months, a spirometry test is performed on the patients and the results of fev1, fvc, RV, tlc are statistically compared in 2 groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231203060254N1**

Registration date: **2024-02-21, 1402/12/02**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-21, 1402/12/02**

Update count: **0**

Registration date

2024-02-21, 1402/12/02

Registrant information

Name

Farzad Rahmandoost

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1594

Email address

fa_rdr@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-09, 1402/10/19

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of zinc supplementation on pulmonary function in adults with cystic fibrosis in Imam Khomeini Hospital in 2023 , Randomize clinical trial

Public title

Investigating the effect of zinc on pulmonary function in adults with cystic fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

They have a history of suffering from cystic fibrosis, which was confirmed by genetic tests that have been done before

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization We use allocation concealment, which refers to the method used to perform a random sequence on study participants, in such a way that the allocated group is not known before the allocation of the individual. By using opaque envelopes sealed with a random sequence (Sequentially numbered, sealed, opaque envelopes), in this method, each of the random sequences created is recorded on a card, and the cards are placed inside the envelopes in order are placed In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box in order. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes is opened in order and assigned to a group. That participant is revealed

Blinding (investigator's opinion)

Double blinded

Blinding description

The trial is conducted in a triple-blind manner, so that the patient, the doctor, and the person who gives the medicine to the patients do not know the type of medicine so that the results can be judged. Patients are

informed about the type of study and full treatment benefits.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Imam Khomeini Hospital NO 12. Tehran Province, Tehran, at the end of Keshavarz Blvd

Street address

Imam Khomeini Hospital NO 12. Tehran Province, Tehran, at the end of Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-11-28, 1402/09/07

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.340

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**

Spirometry test is performed and its results of fev1, fvc, RV, tlc are statistically compared in 2 groups.

Timepoint

Finally after 3 months

Method of measurement

Spirometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Clinical group 30 mg zinc tablets are given to patients daily. In the second group of patients, they have previously suffered from cystic fibrosis, which was diagnosed with genetic tests, and in both groups of patients, they did not mention a history of lung disease or cardiovascular disease. During the period of 3 months, regularly in the morning. The patients in the first group are given 30 mg zinc supplement

Category

Treatment - Drugs

2

Description

Intervention group: They have a history of suffering from cystic fibrosis, which was confirmed by genetic tests that have already been done, and as a clinical group, 30 mg zinc tablets are given to patients daily.

Category

Treatment - Drugs

3

Description

Control group: Control group: In the second group, patients have previously suffered from cystic fibrosis, which has been diagnosed with genetic tests, and in both groups of patients, they do not mention a history of lung disease or cardiovascular disease. It is without zinc supplement, 1 pill is given daily and patients take the pill regularly for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Farzad Rahman Dost

Street address

Keshavarz Blvd, Imam Khomeini Hospital, Tehran

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Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farzad rahmandost

Street address

NO 12 . Blv keshavarz Ave, Imam Khomieni Hospital

City

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Postal code

1419733141

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fa_rdr@yahoo.com

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

Farzad rahmandost

Position

Specialist assistant in lung diseases

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

No 12. Blv Keshavarz Tehran Province, Tehran, at the end of Keshavarz Blvd

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

Tehran University of Medical Sciences

Full name of responsible person

Farzad Rahman Dost

Position

Specialist assistant in lung diseases

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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

Tehran University of Medical Sciences

Full name of responsible person

Farzad Rahman Dost

Position

Lung specialist assistant

Latest degree

Specialist

Other areas of specialty/work

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Email

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

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Spirometry results in patients

When the data will become available and for how long

Access starts 1 year after the results are ready

To whom data/document is available

Researchers in different universities of the world by presenting valid documents

Under which criteria data/document could be used

It is sent in an analyzed form with a valid P value

From where data/document is obtainable

To Dr. Rahman Dost and his email

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

After viewing the identification documents and confirming the identity documents, the documents will be sent as soon as possible.

Comments