Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of magnesium sulfate nebulization in children with cystic fibrosis

Protocol summary

Study aim
Investigating the application of magnesium sulfate nebulization in children with cystic fibrosis

Design
A triple blinded , randomization, phase 3 clinical trial with two arm parallel groups design of 34 patients.

Settings and conduct
During the sampling , first stage data will be collected from the patients. which includes performing a basic spirometry and completing the schwachman form. Then the desired intervention including drug and placebo will be done in each of the groups. Nebulization is performed once in the morning and once in the evening. The intervention will be continued for 4 weeks and then, spirometry will be done again and the completion of schwachman tool. Then the findings will be compared before and after.During the daily intervention period, children are followed up in terms of cardio-respiratory symptoms, nerve reflexes, vital signs and any symptoms of drug allergy or poisoning. The place of sampling is the Cystic Fibrosis Clinic of AKBAR Hospital in mashhad, but the place of intervention is at the patient's home, along with other treatment regimens for the child.

Participants/Inclusion and exclusion criteria
Entry criteria: suffering from cystic fibrosis; over 6 years old; ability to perform spirometry; FEV1 above 60%. Exit criterion: non-cooperation in the continuation of the intervention; drug intolerance; nebulizer intolerance; The patient's entry into the exacerbation phase; Inability to perform spirometry.

Intervention groups
The intervention group in the current study is all patients with cystic fibrosis who meet the inclusion criteria and receive the desired intervention in the current study, which is magnesium sulfate nebulization.

Main outcome variables
Spirometric FEV1 index; Spirometric FVC; Spirometric FEV1/FVC index; Spirometric FEF25-75 index; The score obtained from the schwachman tool

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231031059919N1**
Registration date: **2024-01-08, 1402/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-08, 1402/10/18**
Update count: **0**

Registration date
2024-01-08, 1402/10/18

Registrant information

Name
mitra zibaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3867 0079

Email address
mitrazibaei@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of magnesium sulfate nebulization in children with cystic fibrosis

Public title
Investigating the effect of magnesium sulfate nebulization in children with cystic fibrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from cystic fibrosis Over 6 years old Ability to perform spirometry FEV1 above 60%
Exclusion criteria:
Nnon-cooperation in the continuation of the intervention Drug intolerance Nebulizer intolerance The patient's entry into the exacerbation phase Inability to perform spirometry
Age
From **6 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
In the current study, sampling will be done using the available method. Allocation of research units to control and intervention groups is done by randomization and block method. The purpose of adopting this method is to avoid significant imbalances in the number of participants assigned to each group. Block randomization guarantees that there is no significant imbalance between the groups at any time during the randomization, and at certain points the number of participants in each group is equal. . Then the list of possible blocks is written including AABB(1)- ABAB(2)- ABBA(3)-BBAA(4)- BABA(5)- BAAB(6)) and includes 6 possible blocks. At the time of sampling, between the numbers 1 to 6, which are the numbers of the blocks, a simple lottery will be done by chance, and 4 random samplings will be done based on the block numbers obtained from the lottery. This method will be repeated until the sample volume is completed. Randomization will be done using https://www.randomizer.org/.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to comply with the principle of blinding, the study of the control group was carried out with a placebo (normal saline, which is provided to the parents of the control group in packages with the same shape as the vial of magnesium sulfate or the same drug with a different label A or B) in the same order as in the case of the control group. It was said that the intervention will be implemented.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences Ethics Committee
Street address
Mashhad University of Medical Sciences, Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2023-10-08, 1402/07/16
Ethics committee reference number
IR.MUMS.REC.1402.193

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
FEV1 index of spirometry in children with cystic fibrosis
Timepoint
At the beginning of the intervention and after 4 weeks at the end of the intervention
Method of measurement
Spirometry

2

Description
Spirometric FVC index in children with cystic fibrosis
Timepoint
At the beginning of the intervention and after 4 weeks at

the end of the intervention

Method of measurement

Spirometry

3

Description

Spirometric FEV1/FVC index in children with cystic fibrosis

Timepoint

At the beginning of the intervention and after 4 weeks at the end of the intervention

Method of measurement

Spirometry

4

Description

Spirometric FEF25-75 index in children with cystic fibrosis

Timepoint

At the beginning of the intervention and after 4 weeks at the end of the intervention

Method of measurement

Spirometry

5

Description

The score obtained from the Schwach-Man instrument in children with cystic fibrosis

Timepoint

At the beginning of the intervention and after 4 weeks at the end of the intervention

Method of measurement

Spirometry

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: Cystic fibrosis patients who meet the inclusion criteria. During the sampling, first stage data will be collected from the patients. which includes performing a basic spirometry and completing the Shuvak Man form. Then the desired intervention including medicine will be carried out. The intervention includes the drug magnesium sulfate in the amount of 0.75 cc. The intervention will continue for 4 weeks and after 4 weeks, spirometry will be done again and the completion of the Shavach Man tool. Then the findings in the two groups will be compared before and after. Before and at the end of the intervention (one month after the start of the intervention), the magnesium blood level of children in the intervention and control groups will be measured. During the daily intervention period, children are followed up in terms of cardio-respiratory symptoms, nerve reflexes, vital signs and any symptoms of drug allergy or poisoning.

Category

Treatment - Drugs

2

Description

Control group: patients with cystic fibrosis who meet the inclusion criteria. During the sampling from each of the intervention and control groups, first stage data will be collected from the patients. which includes performing a basic spirometry and completing the Shuvak Man form. Then the desired intervention will be carried out including medication. The placebo intervention is normal saline in the amount of 0.75 cc, and after 4 weeks, spirometry will be done again and the completion of the Shuvach instrument. Then the findings in the two groups will be compared before and after. Before and at the end of the intervention. The magnesium blood level of children in two intervention and control groups is measured. In case of any problem, the drug will be stopped immediately and the patient's safety protocol will be followed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cystic Fibrosis Clinic, Akbar Mashhad Hospital

Full name of responsible person

Mitra Zibaei

Street address

in front of Shahid Kaveh 14, Shahid Kaveh Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9178897157

Phone

+98 51 3871 3801

Email

ak.pr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghoddi

Street address
Vice President of Research and Technology, Qurashi Building, next to Hoize Cinema, Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
vcresraech@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
Mitra Zibaei
Position
pediatric resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Qurashi Building, next to Hoize Cinema,University St
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
mitrazibaei@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mitra Zibaei
Position
pediatric resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Qurashi Building, next to Hoize Cinema, Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
mitrazibaei@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mitra Zibaei
Position
pediatric resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Qurashi Building, next to Hoize Cinema, Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
mitrazibaei@gmail.com

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