

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | implemented.                                   |                                                                                       |
| <b>Public title</b>                                                                         | Investigating the effect of magnesium sulfate nebulization in children with cystic fibrosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Placebo</b>                                 | Used                                                                                  |
| <b>Purpose</b>                                                                              | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Assignment</b>                              | Parallel                                                                              |
| <b>Inclusion/Exclusion criteria</b>                                                         | <b>Inclusion criteria:</b><br>Suffering from cystic fibrosis Over 6 years old Ability to perform spirometry FEV1 above 60% <b>Exclusion criteria:</b><br>Non-cooperation in the continuation of the intervention Drug intolerance Nebulizer intolerance The patient's entry into the exacerbation phase Inability to perform spirometry                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Other design features</b>                   |                                                                                       |
| <b>Age</b>                                                                                  | From 6 years old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Secondary Ids</b>                           | empty                                                                                 |
| <b>Gender</b>                                                                               | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Ethics committees</b>                       |                                                                                       |
| <b>Phase</b>                                                                                | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <u>1</u>                                       |                                                                                       |
| <b>Groups that have been masked</b>                                                         | <ul style="list-style-type: none"> <li>Participant</li> <li>Outcome assessor</li> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Ethics committee</b>                        |                                                                                       |
| <b>Sample size</b>                                                                          | Target sample size: 34                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Name of ethics committee</b>                | Mashhad University of Medical Sciences Ethics Committee                               |
| <b>Randomization (investigator's opinion)</b>                                               | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Street address</b>                          | Mashhad University of Medical Sciences, Daneshgah St.                                 |
| <b>Randomization description</b>                                                            | 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 <a href="https://www.randomizer.org/">https://www.randomizer.org/</a> . | <b>City</b>                                    | Mashhad                                                                               |
| <b>Blinding (investigator's opinion)</b>                                                    | Triple blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Province</b>                                | Razavi Khorasan                                                                       |
| <b>Blinding description</b>                                                                 | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Postal code</b>                             | 9138813944                                                                            |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Approval date</b>                           | 2023-10-08, 1402/07/16                                                                |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Ethics committee reference number</b>       | IR.MUMS.REC.1402.193                                                                  |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Health conditions studied</b>               |                                                                                       |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <u>1</u>                                       |                                                                                       |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Description of health condition studied</b> | Cystic fibrosis                                                                       |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>ICD-10 code</b>                             | E84.0                                                                                 |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>ICD-10 code description</b>                 | Cystic fibrosis with pulmonary manifestations                                         |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Primary outcomes</b>                        |                                                                                       |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <u>1</u>                                       |                                                                                       |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Description</b>                             | FEV1 index of spirometry in children with cystic fibrosis                             |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Timepoint</b>                               | At the beginning of the intervention and after 4 weeks at the end of the intervention |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Method of measurement</b>                   | Spirometry                                                                            |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <u>2</u>                                       |                                                                                       |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Description</b>                             | Spirometric FVC index in children with cystic fibrosis                                |
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Timepoint</b>                               | 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