Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effects of camel milk in spirometry parameters in over 6 year’s children with Cystic Fibrosis lung disease

Protocol summary

Study aim

Evaluation the effects of camel milk in spirometry parameters in over 6 year’s children with Cystic Fibrosis lung disease

Design

Two arm parallel groups randomised trial with blinded postoperative care and outcome assessment and performed on 60 patients aged over 6 years (30 people in each group)

Settings and conduct

This clinical trial is conducted on patients with Cystic Fibrosis who refer to Akbar Hospital clinic in Mashhad. Patients are randomly divided into two groups. The first group will receive only airway clearance therapies(Hypertonic Saline, Inhaled shortacting beta-2 agonist, Azithromycin) and 300 milliliter of cow milk per day as a placebo. The second group, in addition to drug treatment, will receive 300 milliliter of pasteurized camel milk per day for two months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Over 6 year’s children with Cystic Fibrosis lung disease undergoing airway Clearance Treatment 2. The patient is not in the acute exacerbation phase of the disease 3. Those who have FEV1 more than 60% in spirometry 4. Those who have not a severe cough and sputum. Exclusion criteria: 1.Those who are allergic to cow's milk 2.Those who do not cooperate properly in spirometry 3.Those who are hospitalized

Intervention groups

Control group: Patients will receive airway clearance therapies(Hypertonic Saline, Inhaled shortacting beta-2 agonist, Azithromycin) and 300 milliliter of cow milk per day as a placebo. Intervention group: in addition to drug treatment, will receive 300 milliliter of pasteurized camel milk per day for two months.

Main outcome variables

more than 10% increase in FEV1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210914052477N1**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Toktam Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 3977

Email address

kheirabadit981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of camel milk in spirometry parameters in over 6 year’s children with Cystic Fibrosis lung disease

Public title
Evaluation the effects of camel milk on treatment of children with Cystic Fibrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Over 6 year’s children with Cystic Fibrosis lung disease undergoing airway Clearance Treatment The patient is not in the acute exacerbation phase of the disease The patient has completed the Informed consent Form Those who have FEV1 more than 60% in spirometry
Exclusion criteria:
Those who are allergic to cow's milk Those who have a severe cough and sputum Those who are hospitalized Those who do not cooperate properly in spirometry
Age
From **6 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to either control or intervention groups according to a random number table provided by a computer (simple randomization). Allocation Concealment is done using sealed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and patient outcome assessment will be unaware of Intervention and control groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2021-08-15, 1400/05/24
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.290

Health conditions studied

1

Description of health condition studied
Cystic Fibrosis lung disease in children
ICD-10 code
E84
ICD-10 code description
Cystic fibrosis

Primary outcomes

1

Description
Patients with Expiratory Volume in First Second (FEV1) greater than 60%
Timepoint
At the beginning of the study (before the intervention) and two months after beginning milk use (after the intervention)
Method of measurement
spirometer device

Secondary outcomes

1

Description
Percentage of patient whose Forced Expiratory Volume in First Second (FEV1) increase 10%
Timepoint
At the beginning of the study (before the intervention) and two months after beginning milk use (after the intervention)
Method of measurement
spirometer device

Intervention groups

1

Description
Control group: Patients will receive airway clearance therapies(Hypertonic Saline, Inhaled shortacting beta-2 agonist, azithromycin) and 300 milliliter of cow milk per

day as a placebo.

Category

Treatment - Drugs

2

Description

Intervention group: In addition to drug treatment, will receive 300 milliliter of pasteurized camel milk per day for two months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar children Hospital

Full name of responsible person

Dr Seyed Javad Sayedi

Street address

Akbar children Hospital, In front of Shahid Kave 14, Shahid Kaveh sq

City

Mashhad

Province

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9139963185

Phone

+98 51 3870 9202

Email

SayediJ@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Postal code

9138813944

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ramresearch@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

Dr Seyed Javad Sayedi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments