

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigation of the effects of camel milk on spirometric parameters of children aged over 6 years with asthma

Protocol summary

Study aim

Determination of the effect of camel milk on spirometric parameters of children aged over 6 years with asthma who refer to Doctor Sheikh Hospital

Design

This clinical trial is randomized and performed on 50 patients aged over 6 years (25 people in each group) without blinding and consists of control and parallel groups

Settings and conduct

This clinical trial is conducted on patients with asthma who refer to Doctor Sheikh Hospital in Mashhad. Patients will be provided with necessary advice on avoiding allergen (edible and inhalable) orally and in written form. Patients are randomly assigned to 2 groups. Control group receives medication treatment and the second group, in addition to the medication treatment, receives 200 cc of pasteurized camel milk daily for 2 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged over 6 years with asthma classified as "not well control" in spirometry according to Nelson's book, Forced Expiratory Volume in First Second (FEV1) is 60-80% and Forced Expiratory Volume in First Second/Forced Vital Capacity (FEV1/FVC) is 75-80%. Patients are under controller therapy. Patients are not under asthma attack. Exclusion criteria: Asthma attack during the investigation period, unwillingness to continue participation in the study, creation of any sensitivity and intolerance to camel milk during the course

Intervention groups

Control group: Patients will receive medication treatment (inhaled corticosteroids, montelukast and long-acting beta-agonists) according to the standard protocol. Intervention group: In addition to medication treatment (inhaled corticosteroids, montelukast and long-acting beta-agonists), patients will receive 200 cc of pasteurized camel milk daily for 2 months.

Main outcome variables

more than 80% change in FEV1 and FEV1/FVC

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170813035653N2**

Registration date: **2018-12-09, 1397/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-09, 1397/09/18**

Update count: **0**

Registration date

2018-12-09, 1397/09/18

Registrant information

Name

Seyed Javad Sayedi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3724 9421

Email address

sayedij@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-07, 1396/11/18

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of camel milk on spirometric parameters of children aged over 6 years with asthma

Public title

Investigation of the effects of camel milk on children with asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged over 6 years with asthma who are classified as "not well control" according to Nelson's book Forced Expiratory Volume in First Second (FEV1) is 60-80% and Forced Expiratory Volume in First Second/Forced Vital Capacity (FEV1/FVC) is 75-80% in spirometry. Patients are under controller therapy Patients are not under asthma attack

Exclusion criteria:

Asthma attack during the investigation period
Unwillingness to continue participation in the study
Creation of any sensitivity and intolerance to camel milk during the course

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

2017-12-13, 1396/09/22

Ethics committee reference number

IR.MUMS.fm.REC.1396.555

Health conditions studied

1

Description of health condition studied

Asthma in children

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Percentage of people whose Forced Expiratory Volume in First Second (FEV1) exceeds 80%

Timepoint

At the beginning of the study (before the intervention) and two months after beginning drug use (after the intervention)

Method of measurement

spirometer device

2

Description

Percentage of people whose Forced Expiratory Volume in First Second/Forced Vital Capacity (FEV1/FVC) exceeds 80%.

Timepoint

At the beginning of the study (before the intervention) and two months after beginning drug use (after the intervention)

Method of measurement

spirometer device

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients will receive medication treatment (inhaled corticosteroids, montelukast and long-acting beta-agonists) according to the standard protocol.

Category

Treatment - Drugs

2**Description**

Intervention group: In addition to medication treatment (corticosteroids, montelukast and long-acting beta-agonists according to the standard protocol), patients will receive 200 cc of pasteurized camel milk daily for 2 months.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr Sheikh hospital

Full name of responsible person

Dr seyed Javad Sayedi

Street address

Dr Sheikh hospital, Taheri Ave, Tohid Sq.

City

Mashhad

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9139963185

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+98 51 3727 3943

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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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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Dr Sheikh hospital, Taheri Ave, Tohid Sq.

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr seyed Javad Sayedi

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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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