Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Province
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Postal code
9139963185
Phone
+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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9138813944
Phone
+98 51 3841 2081
Email
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
Street address
Dr Sheikh hospital, Taheri Ave, Tohid Sq.
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Person responsible for scientific inquiries

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Full name of responsible person
Dr seyed Javad Sayedi
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr seyed Javad Sayedi

Position

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Latest degree

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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