Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Flaxseed Syrup on clinical manifestation of the pediatric asthma

Protocol summary

Study aim
Determining the effect of flaxseed syrup on the clinical symptoms of asthma in children 5 to 17 years old referred to the pulmonary clinic of Mofid Children's Hospital in 1400

Design
Clinical trial, with control group, non-blind, randomized, phase 3, on 80 patients Randomized with a table of random numbers and 4 blocks

Settings and conduct
This study will be done at pulmonary clinic of Mofid's children hospital. Patients enrolled in the study are divided into intervention and control groups, and both groups receive classic asthma (fluticasone spray 125 micrograms 1 puff every 12 hours and salbutamol spray in case of exacerbation of symptoms). The intervention group also receives flaxseed syrup. At the beginning and end of the study (end of week 8) all patients will be evaluated by taking complete history, doing clinical examination and filling questionnaires (CACT (Children Asthma Control Test) for children under 12 years and ACT (Asthma Control Test) for children 12-17 years) . Finally the results of the two groups are compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 5-17 years, with mild to moderate persistent asthma, willingness to participate in the study Non-inclusion criteria: ages less than 5 or more than 17 years, suffering from a variety of underlying respiratory diseases

Intervention groups
Both groups will receive classic asthma medication. The intervention group will also receive flaxseed syrup in addition to this treatment

Main outcome variables
Asthma control facilitation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210801052048N1**
Registration date: **2021-09-27, 1400/07/05**
Registration timing: **prospective**

Last update: **2021-09-27, 1400/07/05**
Update count: **0**

Registration date
2021-09-27, 1400/07/05

Registrant information

Name
Soroush Samari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-02, 1400/07/10

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Flaxseed Syrup on clinical manifestation of the pediatric asthma

Public title
The effect of Flaxseed Syrup on clinical manifestation of the pediatric asthma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Asthmatic patients between 5-17 years old referring to respiratory diseases clinic at Mofid children hospital, Tehran in 1400
Exclusion criteria:
unwillingness to participate in the study Suffering from severe asthma requiring hospitalization Suffering from other disease such as CF, BPD, heart failure, Tracheobronchomalacia, GERD, bronchiectasis, PTE and sarcoidosis Using ASA, beta blockers or NSAIDs Sensitivity to flaxseed and honey syrup components Suffering from acute asthma attack
Age
From **5 years** old to **17 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: block Randomization unit: individual Randomization tool: Randomization number table Sequence making method: In a table of random numbers, a number is randomly selected from the table and the next numbers are selected in a row or column in the up, down, left or right direction. Because the number of modes of 4 blocks for two groups is 6 modes, numbers higher than 6 and zero are ignored in the table and each digit specifies the desired block.
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 Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2021-08-31, 1400/06/09
Ethics committee reference number
IR.SBMU.MSP.REC.1400.321

Health conditions studied

1

Description of health condition studied
Mild persistent asthma, uncomplicated
ICD-10 code
J45.30
ICD-10 code description
Mild persistent asthma, uncomplicated

2

Description of health condition studied
Moderate persistent asthma, uncomplicated
ICD-10 code
J45.40
ICD-10 code description
Moderate persistent asthma, uncomplicated

Primary outcomes

1

Description
Dyspnea based on ACT and CACT questionnaires, history and physical examination
Timepoint
Filling in ACT and CACT questionnaires at the beginning of the study and at the end of week 8, history and examination at the beginning of the study and at the end of weeks 4 and 8, telephone history at the end of weeks 2 and 6
Method of measurement
ACT and CACT questionnaires (Asthma Control Test & Children Asthma Control Test), visit of a pediatric specialist in respiratory diseases

2

Description
Wheezing based on ACT and CACT questionnaire and history or hearing examination
Timepoint
Filling in ACT and CACT questionnaires at the beginning of the study and at the end of week 8, history and examination at the beginning of the study and at the end of weeks 4 and 8, telephone history at the end of weeks 2 and 6

Method of measurement
ACT and CACT questionnaires (Asthma Control Test & Children Asthma Control Test), visit of a pediatric specialist in respiratory diseases

3

Description
Cough based on ACT and CACT questionnaires, history and physical examination
Timepoint
Filling in ACT and CACT questionnaires at the beginning of the study and at the end of week 8, history and examination at the beginning of the study and at the end of weeks 4 and 8, telephone history at the end of weeks 2 and 6
Method of measurement
ACT and CACT questionnaires (Asthma Control Test & Children Asthma Control Test), visit of a pediatric specialist in respiratory diseases

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Flaxseed syrup is prepared by boiling flaxseed in water and then adding honey until it reaches a suitable consistency and taste. Microbial preservatives are added and physical and chemical quality control tests are performed on the product. This syrup with a daily dose of 5-10 cc (5 cc for children weighing less than 30 kg and 10 cc for weights over 30 kg) in three servings (0.8 mg in 5 cc syrup) for group members Intervention is prescribed. All of these people will also be treated for mild to moderate persistent asthma (with fluticasone and salbutamol sprays).
Category
Treatment - Drugs

2

Description
Control group: These people will only receive the classic treatment for mild to moderate persistent asthma. (Fluticasone spray 125 micrograms 1 puff every 12 hours and salbutamol spray in case of acute exacerbation of symptoms)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Children's Hospital
Full name of responsible person
Dr. Shamsollah Nouri Pour
Street address
Mofid Children's Hospital, Shariati St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Alireza Zali
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Soroush Samari Kermani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Medical doctor

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Person responsible for updating data

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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