

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

Phone

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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

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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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Province

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Postal code

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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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Position

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Latest degree

Medical doctor

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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