

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of inhaled beclomethasone with or without montelukast in the control of pediatric persistent asthma

Protocol summary

Summary

Purpose: The effect of the oral montelukast compared to the inhaled beclomethasone on the control of pediatric persistent asthma. Inclusion criteria: Children aged 6-10 years with persistent asthma symptoms. (The criterion for asthma diagnosis was based on GINA considering the history, clinical examination and respiratory function test). Exclusion criteria: Children with lung infections, any underlying illness (simultaneous cardiac disease, antihistamine use, having any illness and taking other medications). Population: Children with persistent asthma, referring to Amirkola Children's Hospital in 2016. Allocation of samples will do as block randomization with four blocks in two groups: ABBA/BAAB/BBAA/AABB/ABAB/ABBA/BAAB/BBAA/AABB/ABAB/ABBA/BAAB/BBAA/AA BB/ABAB/ Also, test and its interpretation will perform by the relevant technician and master, respectively as single blind. Sample size: Considering the admission of 82, 45% for both groups, 40 patients per group and totally 80 children. Secondary outcomes: Quality of night sleep and absence from school. Primary outcome: Improvement in FEV1 values. Intervention: Patients of one group will receive 100 micrograms of inhaled beclomethasone three times a day with 5 mg of montelukast tablets daily, while another group only will receive 100 micrograms of inhaled beclomethasone three times a day. Before and 3 months after treatment, the FEV1, IgE, eosinophilia, night sleep quality (sleep deprivation) and absence from school will be recorded. At the end of the treatment for two groups in the questionnaire (by one person) and also in the third month, the probable complications of montelukast (headache, diarrhea, nausea and hives) will be recorded. The FEV1 response to treatment is greater than 80%.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092036286N1**

Registration date: **2017-10-17, 1396/07/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

Name

Dr Athena Modanlu

Name of organization / entity

Non-Communicable Pediatric Diseases Research Center, Health Research Institute, Babol University of

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice- Chancellor for Research Technology Affairs of Babol University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inhaled beclomethasone with or without montelukast in the control of pediatric persistent asthma

Public title

Effect of beclomethasone in the control of pediatric asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pediatrics aged 6 to 10 years; Pediatrics with persistent asthma symptoms; referred to the Center during the study; Exclusion criteria: Pediatrics with lung infections; Pediatrics any underlying illness such as simultaneous cardiac disease; Antihistamine use; Having any illness; Taking other medications;

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Babol University of Medical Sciences

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Vice- Chancellor for Research Technology Affairs,
Babol University of Medical Sciences, Ganjafroz
Street, Babol, Mazandaran Province, IR Iran.

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4717647745

Approval date

2017-08-27, 1396/06/05

Ethics committee reference number

MUBABOL.HRI.REC.1396.38

Health conditions studied**1****Description of health condition studied**

Pediatric Persistent Asthma

ICD-10 code

J45.0

ICD-10 code description

Predominantly allergic asthma

Primary outcomes**1****Description**

FEV1

Timepoint

Before and 3 months after treatment

Method of measurement

With spirometry

Secondary outcomes**1****Description**

Go to school

Timepoint

At the end of the treatment

Method of measurement

Take report from parent and completion in the questionnaire

2**Description**

Night sleep quality (sleep deprivation)

Timepoint

At the end of the treatment

Method of measurement

Take report from parent and completion in the questionnaire

Intervention groups**1****Description**

First group: Patients of one group will receive 100 micrograms of inhaled beclomethasone three times a day with 5 mg of montelukast tablets daily.

Category

Treatment - Drugs

2**Description**

Second group: Patients only will receive 100 micrograms of inhaled beclomethasone three times a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola Children's Hospital, Babol University of Medical Sciences

Full name of responsible person

Dr Athena Modanlu

Street address

Amirkola Children's Hospital, Emam Ave, Amirkola, Babol, Mazandaran Province, IR Iran

City

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Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences

Full name of responsible person

Dr Aliakbar Moghaddamnia

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Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran Province, IR Iran.

City

Babol

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Non-Communicable Pediatric Diseases Research Center, Health Research Institute, Babol University of

Full name of responsible person

Dr Iraj Mohammadzadeh

Position

Pediatric clinical Immunology & allergy

Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty