

# 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

+98 11 3234 6963

##### Email address

a.modanlu@gmail.com

#### 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

**Street address**

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

**City**

Babol

**Postal code**

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**

Amirkola- Babol

### Other areas of specialty/work

**Street address**

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4731741151

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irjmoh2000@yahoo.com;  
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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

**Street address**

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

**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

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## Person responsible for updating data

### 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*