

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### " Therapeutic effect of Fluticasone and Montelukast in children younger than 5 years with recurrent wheeze"

#### Protocol summary

##### Summary

Fluticasone and Montelukast therapy in this study of wheezy children under 5 years. This is randomized clinical trial. Patients referred to the Golgasht clinic or Children hospital clinic were randomly divided into two groups. Inclusion criteria: (no abnormalities underlying anatomic disease: family history of allergies and asthma patient ) And exclusion criteria: (anatomical issues such as the children with Gastroesophageal Reflux Disease: Cystic fibrosis : underlying medical condition such as cardiovascular problems they are not in the study).68 patients should be monitored every 2-4 weeks for 6 months to 6 months to be seen. Assessed response to treatment is based on clinical history and examination. Outcome is reduction of cough and wheeze and dyspnea

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201204099429N1**

Registration date: **2013-09-08, 1392/06/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-09-08, 1392/06/17

##### Registrant information

###### Name

Mahnaz Sadeghi shabesteri

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1336 4650

###### Email address

sadeghim@tbzmed.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

"Tabriz University of Medical Science"

###### Expected recruitment start date

2013-08-29, 1392/06/07

###### Expected recruitment end date

2014-03-27, 1393/01/07

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

" Therapeutic effect of Fluticasone and Montelukast in children younger than 5 years with recurrent wheeze"

###### Public title

" Effects of Montelukast treatment in asthmatic children under 5 years"

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: (no abnormalities underlying anatomic disease: family history of allergies and asthma patient ) And exclusion criteria: (anatomical issues such as the children with Gastroesophageal Reflux Disease: Cystic fibrosis : underlying medical condition such as cardiovascular problems they are not in the study).

###### Age

To 5 years old

###### Gender

Both

###### Phase

3

### Groups that have been masked

No information

### Sample size

Target sample size: 68

### Randomization (investigator's opinion)

Randomized

### Randomization description

### 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

"Tabriz University of Medical Science"

##### Street address

"Tabriz, Golghasht street, Azadi Avenue"

##### City

Tabriz

##### Postal code

51666-16471

#### Approval date

2012-08-25, 1391/06/04

#### Ethics committee reference number

9182

## Health conditions studied

### 1

#### Description of health condition studied

"Asthma in children"

#### ICD-10 code

J40.J47

#### ICD-10 code description

Asthma

## Primary outcomes

### 1

#### Description

"Wheeze intensity"

#### Timepoint

The severity of wheezing diagnosed based on clinical examination and recorded every 2-4 weeks to 6 months after starting treatment with Montelukast 5 mg daily and Fluticasone 100 mcg twice a day, patients are followed up.

### Method of measurement

Physical examination

## Secondary outcomes

### 1

#### Description

"Cough intensity"

#### Timepoint

The severity of coughing diagnosed based on clinical examination and recorded every 2-4 weeks to 6 months after starting treatment with Montelukast 5 mg daily and Fluticasone 100 mcg twice a day, patients are followed up.

#### Method of measurement

Physical examination

### 2

#### Description

"Dyspnea intensity"

#### Timepoint

The severity of dyspnea diagnosed based on clinical examination and recorded every 2-4 weeks to 6 months after starting treatment with Montelukast 5 mg daily and Fluticasone 100 mcg twice a day, patients are followed up.

#### Method of measurement

Physical examination

## Intervention groups

### 1

#### Description

Intervention: 5 mg montelukast daily

#### Category

Treatment - Drugs

### 2

#### Description

Control: fluticasone 100 mcg spray two puffs twice a day

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

"Children Hospital"

##### Full name of responsible person

"Dr.Mahnaz Sadeghi Shabestari"

##### Street address

Sheshgelan street, Tabriz

##### City

Tabriz

## 2

### Recruitment center

**Name of recruitment center**

"Golghasht Clinic"

**Full name of responsible person**

"Dr.Mahnaz Sadeghi Shabestari"

**Street address**

Golghasht, Azadi Avenue

**City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

"Tabriz University of Medical Sciences, Assistance Research"

**Full name of responsible person**

"Dr.Meshkini"

**Street address**

Golgasht Avenue, Azadi Avenu. Tabriz

**City**

Tabriz

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

Yes

**Title of funding source**

"Tabriz University of Medical Sciences, Assistance Research"

**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**

"Tabriz University of Medical Science"

**Full name of responsible person**

"Maryam Abbasnazhad"

**Position**

"Intern"

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Golghasht street

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

"Children Hospital"

**Full name of responsible person**

"Dr.Mahnaz Sadeghi Shabestari"

**Position**

Associate and Specialty Allergy and Immunology  
Pediatric

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## Person responsible for updating data

### Contact

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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*