

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Therapeutic effects of Montelukast and Fluticasone in children under 5 years with recurrent wheeze

Protocol summary

Summary

The purpose of this study is to investigate the effect of Fluticasone and Montelukast in recurrent wheeze, ie more than three times a year in children under 5 years. The total sample size is 68 children and sampled centers are Tabriz Children's hospital and Golgasht clinic and children will be randomly divided into two groups. For 34 children will be administered Montelukast tablet 5 mg daily till one month after the baseline visit and for 34 children Fluticasone spray 100 mcg 2 puffs twice a day for 1 month and adjust the dose will be done after one month visit. We visit the child every month for 6 months, and outcomes are assessed based on clinical examination, including coughing, wheezing and shortness of breath .This study is designed for a year. Before starting treatment, inclusion and exclusion criteria are assessed by questionnaire and consent form from parents is completed. Inclusion criteria: children under 5 years, with more than 3 times the number of wheezing in clinical studies and no clinical evidence of other predisposing factors. Exclusion criteria: children under 5 years who have evidence of other predisposing factors for wheezing, such as Gastro Esophageal Reflux Disease, Cystic Fibrosis, heart disease, airway disease, congenital anatomical issues.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309079429N3**

Registration date: **2013-09-20, 1392/06/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-20, 1392/06/29

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 Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of Montelukast and Fluticasone in children under 5 years with recurrent wheeze

Public title

Montelukast and Fluticasone effect in wheeze

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children under 5 years, with more than 3 times the number of wheezing in clinical studies and no clinical evidence of other predisposing factors. Exclusion criteria: children under 5 years who have evidence of other predisposing factors for wheezing, such as Gastro

Esophageal Reflux Disease, Cystic Fibrosis, heart disease, airway disease, congenital anatomical issues.

Age

To 5 years old

Gender

Both

Phase

N/A

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**

Research Departement of Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code**Approval date**

2012-06-25, 1391/04/05

Ethics committee reference number

9182

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

asthma

ICD-10 code

J45

ICD-10 code description

J45.0

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

wheeze severity

Timepoint

before intervention and every month after intervention till 6 month

Method of measurement

physical examination and listen breath sounds

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

cough severity

Timepoint

before intervention and every month after intervention till 6 month

Method of measurement

physical examination and ask from parents

2**Description**

dyspnea severity

Timepoint

before intervention and every month after intervention till 6 month

Method of measurement

physical examination and ask from parents

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

For 34 children will be administered Montelukast tablet 5 mg daily till one month after the baseline visit

Category

Treatment - Drugs

2**Description**

for 34 children Fluticasone spray 100 mcg 2 puffs twice a day for 1 month and adjust the dose will be done after one month visit.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Children Hospital

Full name of responsible person

Dr.Mahnaz Sadeghi Shabestari

Street address

Sheshgelan street

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Students Research Comittee of Tabriz University of
Medical Sciences

Street address

Golgasht street

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

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

Medical Faculty

Full name of responsible person

Dr.Mahnaz Sadeghi Shabestari

Position

Immunologist Allergist /Associated Professor

Other areas of specialty/work

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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

