

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

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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

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

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

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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"

Other areas of specialty/work

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Person responsible for scientific inquiries

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Pediatric

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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