

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Montelukast and placebo in the prevention of upper respiratory infections in children 1 to 5 years

Protocol summary

Summary

In this study to reviewing the efficacy of Montelukast in prevention of upper respiratory infections in children whom did not have hyper reactive airway disease, 380 children 1 to 5 years referring to pediatric clinic of Amir Kabir hospital from December 2012 to February 2013, receiving Montelukast or placebo in ratio of one to one in a double blind randomized method. The way is that they are referred to a third person who has placebo and montelukast and he give them placebo or montelukast randomly. A Form of primary information for them to be filled. Then be followed weekly by phone. In addition, each patient Receives a Symptom checklist that includes fever, rhinitis, cough, antipyretic or antibiotic use, physician visits, absences from kindergarten. Each patient will be followed for 12 weeks and during this time the number of attacks of upper respiratory infections are recorded. The data obtained from both cases and controls are compared in general and by age and sex with each other. If someone refuses to continue, he will be replaced by a new one.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012103111339N1**

Registration date: **2012-12-06, 1391/09/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-06, 1391/09/16

Registrant information

Name

Mohammad Hossein Esmaeli Sirchi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Montelukast and placebo in the prevention of upper respiratory infections in children 1 to 5 years

Public title

Montelukast effect in the prevention of respiratory infections

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Lack of hyper reactive airway disease; No history of allergic rhinitis; Not taking any medication for a chronic; Absence of chronic heart disease or chronic respiratory disease: Exclusion criteria: Hyper reactive airway disease (previously treated with bronchodilators in the last three months, Or more than

once treatment in the past year or hospitalization for treatment or prophylaxis in recent years with Montelukast or steroids);History of allergic rhinitis;Taking any medication for a chronic; Chronic heart disease or chronic respiratory disease;Known hypersensitivity to Montelukast;Active URI within one week ago

Age

From **1 year** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **380**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Arak University of Medical Sciences

Street address

Pardis, Sardasht

City

Arak

Postal code

3848176941

Approval date

2012-06-27, 1391/04/07

Ethics committee reference number

91-128-13

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

Common cold

ICD-10 code

J00

ICD-10 code description

Acute nasopharyngitis [common cold]

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

Number of uri attacks

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

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

Otitis media, Pneumonia, Tonsillitis, Pharyngitis

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

2**Description**

The number of weeks that a child has a fever

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

3**Description**

The use of antibiotics or anti-fever

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

4**Description**

Doctor visits

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

5**Description**

Absences from child care

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

6**Description**

Absent parents

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

7

Description

Hospitalization

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

8

Description

Drug reaction

Timepoint

Weekly to 12 weeks

Method of measurement

Call and complete symptom checklist

Intervention groups

1

Description

In this randomized, double-blind study 190 children from 1 to 5 years old referred to Pediatric Clinic of arak Amir Kabir Hospital from 21/11/2012 to 19/2/2013 who do not have hyper reactive airway disease get montelukast(5 mg daily) oral once a day and fills for them an information form then they followed by weekly calls.In addition, each patient Receives a record sheet of fever, rhinitis, cough, antipyretic or antibiotic use, the absence of child care and doctor visits.Each patient will be followed for 12 weeks.

Category

Prevention

2

Description

In this randomized, double-blind study 190 children from 1 to 5 years old referred to Pediatric Clinic of arak Amir Kabir Hospital from 21/11/2012 to 19/2/2013 who do not have hyper reactive airway disease get placebo oral once a day and fills for them an information form then they followed by weekly calls.In addition, each patient Receives a record sheet of fever, rhinitis, cough, antipyretic or antibiotic use, the absence of child care and doctor visits.Each patient will be followed for 12 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir kabir Hospital

Full name of responsible person

Dr Fatemeh Dorreh

Street address

Amir Kabir Hospital, Alamolhoda St.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Saiid Changizi Ashtyani

Street address

Pardis, Sardasht

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Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Fatemeh Dorreh

Position

Assistant Professor

Other areas of specialty/work

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Pediatrician

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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