Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Country

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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 Monteluckast 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 cheklist

2

Description
The number of weeks that a child has a fever

Timepoint
Weekly to 12 weeks

Method of measurement
Call and complete symptom cheklist

3

Description
The use of antibiotics or anti-fever

Timepoint
Weekly to 12 weeks

Method of measurement
Call and complete symptom cheklist

4

Description
Doctor visits

Timepoint
Weekly to 12 weeks

Method of measurement
Call and complete symptom cheklist

5

Description
Absences from child care

Timepoint
Weekly to 12 weeks

Method of measurement
Call and complete symptom cheklist

6

Description
Absent parents

Timepoint

Weekly to 12 weeks
Method of measurement
Call and complete symptom cheklist

7

Description
Hospitalization
Timepoint
Weekly to 12 weeks
Method of measurement
Call and complete symptom cheklist

8

Description
Drug reaction
Timepoint
Weekly to 12 weeks
Method of measurement
Call and complete symptom cheklist

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 montelucast(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
Arak

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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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
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Full name of responsible person
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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