Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Montelukast on urinary symptoms in children with bladder hyperactivity

Protocol summary

Study aim
Evaluation of the effect of Montelukast on urinary symptoms in children with overactive bladder
Design
Clinical trial with control group, with factorial groups, phase 3, on 60 patients.
Settings and conduct
60 children with bladder hyperactivity, referred to the pediatric clinic of Amirkabir Hospital in Arak, Will be divided into two equal groups of Montelukast and the control group. In the Montelukast group, 5 mg (one tablet) of Montelukast tablets daily is given to each child for 10 days, along with the classic treatment of hyperactive bladder, and the control group received only the classic treatment for 10 days. At the beginning and end of the study, mothers of children will be asked questions about their urinary status and will be noted on a checklist.
Participants/Inclusion and exclusion criteria
Inclusion condition: Children with bladder hyperactivity, aged 3-17 years, with a history of allergies: Condition not to enter: History of allergy to Montelukast drug
Intervention groups
The recipient group of Montelukast and classical medicine The control group received classical treatment alone
Main outcome variables
Type of intervention; Frequent urination; Frequent incontinence; Frequent urinary urgency

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210212050333N1**
Registration date: **2021-06-09, 1400/03/19**
Registration timing: **prospective**
Last update: **2021-06-09, 1400/03/19**
Update count: **0**
Registration date
2021-06-09, 1400/03/19

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-06-30, 1400/04/09
Expected recruitment end date
2021-07-31, 1400/05/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Montelukast on urinary symptoms in children with bladder hyperactivity

Public title
The effect of Montelukast on bladder hyperactivity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with bladder hyperactivity 3-17 years old

Exclusion criteria:
History of allergy to Monteluca

Age
From **3 years** old to **17 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not 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
Ethics Committee of Arak University of Medical Sciences

Street address
Shahid Shiroodi St Alam alHuda St.

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Arak

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Postal code
3819693345

Approval date
2021-01-23, 1399/11/04

Ethics committee reference number
IR.ARAKMU.REC.1399.310

Health conditions studied

1

Description of health condition studied
Overactive bladder

ICD-10 code
N39.4

ICD-10 code description
Other specified urinary incontinence

Primary outcomes

1

Description
Frequent urination

Timepoint
Frequent urination was measured at the beginning of the study and 10 days after starting Montelukast

Method of measurement
questionnaire

2

Description
Frequent urgency incontinence

Timepoint
Measuring the incidence of urgent incontinence at the beginning of the study and 10 days after starting Montelukast

Method of measurement
questionnaire

3

Description
Frequent urinary urgency

Timepoint
Measure the frequency of urinary urgency at the beginning of the study and 10 days after starting Montelukata

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Monte lucast 5 mg tablets, one tablet daily for 10 days, with classic treatment

Category
Treatment - Drugs

2

Description
Control group: receiving classical treatment alone for 10 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital
Full name of responsible person
Fateme Dorre
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Sponsors / Funding sources

1

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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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available