

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

###### Name

Somayeh Abbasi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3277 8434

###### Email address

m.h1221@mailfa.com

##### 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.

**City**

Arak

**Province**

Markazi

**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

**Street address**

Shahid Shiroudi St Parstar Sq. Amirkabir Hospital,  
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Masoumeh Kalantari

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info@arakmu.ac.ir

**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

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Darreh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

Somayeh Abbasi

**Position**

Intern student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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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