# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jun 2026

## Evaluation the effect of Montelukast on urinary symptoms in children with bladder pain syndrome

### Protocol summary

**Study aim**
Evaluation of Montelukast effect on children with bladder pain syndrome

**Design**
A randomized clinical trial with control with out blinding,phase 2 on 64 patient. Randomization is performed by using quadruple blocks which is produced by statistical software

**Settings and conduct**
children with bladder pain syndrome and entry criteria are added to the study after getting consent with blocking randomization method in Amirkabir hospital of Arak city.Diagnosis of the disease is confirmed by getting history,checking urine analysis and culture and also sonography to rule out other medical conditions.children with Bps are divided into two groups:(Montelukast receiving) and (control)group.In Montelukast receiving group Monteukast and Oxybutinin are prescribed for each child for 14days and in control group only classic treatment(Oxybutinin) is prescribed for 14days.In the beginning and end of the study the symptoms are checked and added to the prepared checklists.

**Participants/Inclusion and exclusion criteria**
Entry criteria:All 3-18 year old children with bladder pain syndrome and allergy history who were referred to Amirkabir hospital pediatric clinic and were admitted to Amirkabir hospital wards Exit criteria:Allergy history to Montelukast

**Intervention groups**
In Montelukast receiving group Monteukast(chewable tab 5mg) and Oxybutinin(tab 5 mg)are prescribed for each child for 14days and in control group only classic treatment(Oxybutinin) is prescribed. Montelukast :5mg in 3-15 y children,10mg in children who are older than15 daily Oxybutinin: 0.2mg/kg/dose twice a day in children who are under 5 years old and 5 mg twice a day in children who are older than 5

**Main outcome variables**
Comparison of frequency, nocturia,urgency ,incontinency and bladder pain severity before and after intervention in Montelukast receiving group and in control group among children with pain bladder syndrome

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20210628051728N1**
Registration date: **2021-07-08, 1400/04/17**
Registration timing: **prospective**

Last update: **2021-07-08, 1400/04/17**
Update count: **0**

**Registration date**
2021-07-08, 1400/04/17

**Registrant information**

**Name**
Faezeh Akbarzadeh

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 86 3313 5075

**Email address**
faezeakbarzadeh@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-08-02, 1400/05/11

**Expected recruitment end date**
2021-10-22, 1400/07/30

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation the effect of Montelukast on urinary symptoms in children with bladder pain syndrome

**Public title**

The effect of Montelukast on symptoms of children with bladder pain syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All 3-18 year old children with bladder pain syndrome who were referred to Amirkabir hospital pediatric clinic of Arak city All 3-18 year old children with bladder pain syndrome who were admitted to Amirkabir hospital ward of Arak city Allergy history

**Exclusion criteria:**

Allergy history to Montelukast

**Age**

From **3 years** old to **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For dividing patients into two groups block randomization method will be used.This method is used for making balance in allocated cases.The epidemiologist will create randomization sequences by using quadruple blocks(Two cases from control group and two cases from case group) that are produced by the assist of sealed envelope online site and will allocate patients to two groups.As soon as a patient enters the project its status will be determined so the concealment process will be guaranteed.

**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 commitee of Arak University of Medical Sciences

**Street address**

Arak university of medical sciences,Payambare Azam university complex,Basij Square,Sardasht,Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2021-06-12, 1400/03/22

**Ethics committee reference number**

IR.ARAKMU.REC.1400.055

## Health conditions studied

### 1

**Description of health condition studied**

Bladder pain syndrome

**ICD-10 code**

R39.89

**ICD-10 code description**

Other symptoms and signs involving the genitourinary system

## Primary outcomes

### 1

**Description**

decrease nocturia

**Timepoint**

days0-14

**Method of measurement**

questionnaire(numbers)

### 2

**Description**

Alleviate bladder pain

**Timepoint**

days0-14

**Method of measurement**

questionnaire(mild/moderate/severe)

### 3

**Description**

Decrease urinary Incontinency

**Timepoint**

days 0-14

**Method of measurement**

questionnaire(numbers)

### 4

**Description**

Decrease urinary urgency

**Timepoint**
days 0-14
**Method of measurement**
questionnaire(numbers)

**5**

**Description**
Decrease urinary frequency
**Timepoint**
days 0-14
**Method of measurement**
questionnaire(numbers)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Montelukast chewable tablet 5mg in 3-15 year children,10mg in older than 15 year children daily for 14days.This tablet is made in Iran,Dr Abidi pharmaceutical company.Classic treatment consists of Oxybutinin 5mg tablets which is prescribed 0.2mg/kg/dose twice a day in children younger than 5 and 5mg twice a day in older than 5 year old children.It is made in Iran,Iran Daru pharmaceutical company.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Classic treatment consists of Oxybutinin 5mg tablets which is prescribed 0.2mg/kg/dose twice a day in children younger than 5 and 5mg twice a day in older than 5 year old children.It is made in Iran,Iran Daru pharmaceutical company.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Amirkabir hospital
**Full name of responsible person**
Dr Ali Arjmand,Dr Fatemeh Dorreh,Faezeh Akbarzadeh
**Street address**
Amirkabir hospital,Parastar square,Shahid Shirodi Ave,Arak
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Dr Alireza Kamali
**Street address**
Arak university of medical sciences,Payambare Azam university complex,Basij square,Sardasht,Arak
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**Email**
alikamaliir@yahoo.com
**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**
Faezeh Akbarzadeh
**Position**
Intern
**Latest degree**
A Level or less
**Other areas of specialty/work**
General Practitioner
**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
All the individual data of participants

**When the data will become available and for how long**
The access period starts immediately after publishing the results

**To whom data/document is available**
The information will be available for any researcher.

**Under which criteria data/document could be used**
There is no limitation.

**From where data/document is obtainable**
Faezeh Akbarzadeh via faezeakbarzadeh@yahoo.com / Dr.Ali Arjmand via aliarjmand1@yahoo.com /Dr.Fatemeh Dorreh via fatemeh_dorre@yahoo.com/ Dr.Parsa Yousefi via parsayousefichaijan@yahoo.com

**What processes are involved for a request to access data/document**
The applicant must send his request via email while introducing himself and his reason for information access .Then the data will be sent back by email.

**Comments**