Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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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3819693345
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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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3848176941
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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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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