Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation the effect of Montelukast on urinary symptoms in children with pollakiuria

Protocol summary

Study aim
1.Determining the frequency of daily urination in "Receiving Montelukast" group before and after intervention 2. Determining the frequency of daily urination in control group before and after receiving the routine treatment 3.Comparing the frequency of daily urination in the two groups before and after intervention

Design
Randomized clinical trial with control group, on 64 patients. The randomization will be performed by using quadruple blocks which is produced by statistical software

Settings and conduct
The diagnosis will be confirmed by normal U/A, U/C and kidney and urinary tract's sonography. These children will allocated to equal "case" and "control" groups by using randomization methods. At the beginning and end of the 14days of treatment, we will ask the mothers about the urinary symptoms and will note the information in check lists. The study will be performed in Amir Kabir hospital of Arak city.

Participants/Inclusion and exclusion criteria
Inclusion criteria : 1.Children aged 3-18 years with pollakiuria who referred to pediatric clinic of Amir Kabir hospital of Arak 2. Children aged 3-18 years with pollakiuria who hospitalized in wards of Amir Kabir hospital of Arak 3. Having the allergy history Criteria for non-entry to study: 1. History of allergy to Montelukast

Intervention groups
In the receiving Montelukast group Montelukast chewable tablets 5 mg/d are prescribed for 14days in 3-15 years old children and 10mg/d for children older than 15 years old. The both "case" and "control" groups will receive the routine treatment of pollakiuria which is Oxybutynin tablets 5mg.The tablets are prescribed as follows. 0.2mg/kg/dose q12hours in children younger than 5 years old for 14 days (Max dose:15mg/24h) and 5mg/dose q12 h in children older than 5 years old (Max dose: 20mg/24h).

Main outcome variables
frequency of daytime urination before and after intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210626051718N1**
Registration date: **2021-07-15, 1400/04/24**
Registration timing: **prospective**

Last update: **2021-07-15, 1400/04/24**
Update count: **0**

Registration date
2021-07-15, 1400/04/24

Registrant information
Name
Hamideh Bakhtiari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 26 4534 4302
Email address
hamide.bakhtiari@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-01, 1400/05/10

Expected recruitment end date
2021-11-01, 1400/08/10

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 pollakiuria

Public title

The effect of montelukast in treatment of Pollakiuria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All children with pollakiuria aged 3-18 years referred to the pediatric clinic of Amirkabir Hospital in Arak Children with pollakiuria aged 3-18 years who were hospitalized in the pediatric wards of Amirkabir Hospital in Arak History of allergy

Exclusion criteria:

Allergiy history to Montelukast

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are allocated to two groups by block randomization method in which the allocated patients to each group will be equal.In this clinical trial we will use quadruple blocks(consists of 2applicants of case-group and 2 applicants of control-group). These are produced by random allocation software. The concealment is guaranteed by concealing the random allocation with sequentially numbered, sealed, opaque envelopes that the allocated group should not be specified before the individual is assigned.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

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

Arak University of Medical Sciences, University complex of Payambare Azam, Sardasht

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۵

Approval date

2021-06-13, 1400/03/23

Ethics committee reference number

IR.ARAKMU.REC.1400.054

Health conditions studied

1

Description of health condition studied

Pollakiuria (The daytime urinary frequency syndrome)

ICD-10 code

R35.0

ICD-10 code description

Frequency of micturition

Primary outcomes

1

Description

frequency of daytime urination

Timepoint

First at the beginning of the study and then after 14days of receiving treatment

Method of measurement

After 14 days of treatment,the frequency of daytime urination and the exact day which the symptoms had improved will be asked from mothers.Then these information will be noted in check list.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Montelukast chewable tablets 5 mg/d are prescribed for 14days in 3-15 years old children and 10mg/d for children older than 15 years old.This tablet is produced by Dr. Abidi 's pharmaceutical company, Tehran, Islamic republic of Iran.Oxybutynin tablets 5mg as a routine treatment will be prescribed.The tablets are prescribed as follows. 0.2mg/kg/dose q12hours in children younger than 5 years old for 14 days (Max dose:15mg/24h) and 5mg/dose q12 h in children older than 5 years old (Max dose: 20mg/24h).This tablet is

produced by Iran Daru pharmaceutical company, Tehran, Islamic republic of Iran.

Category

Treatment - Drugs

2

Description

Control group: Oxybutynin tablets 5mg as a routine treatment will be prescribed.The tablets are prescribed as follows. 0.2mg/kg/dose q12hours in children younger than 5 years old for 14 days (Max dose:15mg/24h) and 5mg/dose q12 h in children older than 5 years old (Max dose: 20mg/24h).This tablet is produced by Iran Daru pharmaceutical company, Tehran, Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Dr.Ali Arjmand Shabestari, Dr.Fatemeh Dorreh, Hamide Bakhtiari

Street address

Amir Kabir hospital, Parastar square, Shahid Shirodi Ave, Arak

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Province

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Phone

+98 86 3313 4715

Email

info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Arak University of Medical Sciences, Payambare Azam University complex, Sardasht, Arak

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+98 86 3417 3645

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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

Hamideh Bakhtiari

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Hazrat masoome dormitory,University union,Sardasht,Arak

City

Arak

Province

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Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

Name of organization / entity

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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 of the indivisual data of participants

When the data will become available and for how long

The access period stars immediately aftter publishing the results.

To whom data/document is available

The informations will be available for any researcher.

Under which criteria data/document could be used

There is no limitation

From where data/document is obtainable

Hamide bakhtiari via email: hamide.bakhtiari @gmail.com Dr.parsa Yousefichaijan via email:parsayousefichaijan@gmail.com Dr.Fatemeh Dorre via email:fatemeh_dorre@yahoo.com Dr.Ali Arjmand via email:aliarjmand1@yahoo.com

What processes are involved for a request to access data/document

The applicant send his request via email.He should introduce himself completely and mention why he needs the information.Then the data will send back by email.

Comments