Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect and tolerability of Polycitra-k sachet with solution form on correction of urine metabolites and acidosis in treatment of pediatric with nephrolithiasis: Randomized clinical trial

Protocol summary

Study aim

To study the effect of Polycitra-K sachet on the treatment of pediatric urinary stones and comparing it with the solution form of the drug

Design

Patients in two groups with the same diet are treated with a solution or sachet of Polycitra potassium. Patient evaluations include ultrasound, determination of urinary pH and measurement of 24-hour urinary metabolites at baseline, measurement of urinary pH one month later, and finally repetition of initial evaluations at the end of the study (three months after starting treatment).

Settings and conduct

Children and adolescents with kidney stone in two pediatric hospitals (Mofid and Ali-asghar) randomly treated with a solution or sachet of Polycitra- K. Patient evaluations include ultrasound, determination of urinary pH and measurement of 24-hour urinary metabolites at baseline and three months later as well as urinary pH one month later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Children and adolescents between 1 and 16 years of old with kidney stone - On ultrasound, kidney stones are larger than or equal to 5 mm - Without any history of recent urinary tract infection - Have normal kidney function - Without urinary tract anomalies Exclusion criteria: - A child who needs urological intervention during the project. - A child who stops taking medication due to illness such as diarrhea, etc. - Any patient who does not want to continue the project.

Intervention groups

Fifty children or adolescents with kidney stones (one to 16 years old) are randomly divided into two groups of twenty-five patients under treatment with Polycitra-K sachets or solution.

Main outcome variables

Changes in kidney stone size, blood creatinine, urine pH and 24-hour urinary citrate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045244N2**
Registration date: **2021-06-01, 1400/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-01, 1400/03/11**
Update count: **0**

Registration date

2021-06-01, 1400/03/11

Registrant information

Name

Maryam Taheri

Name of organization / entity

Urology and Nephrology Research Center,Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2256 7222

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect and tolerability of Polycitra-k sachet with solution form on correction of urine metabolites and acidosis in treatment of pediatric with nephrolithiasis: Randomized clinical trial

Public title
Effect of Polycitra-K sachet in pediatric kidney stone
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
- Children and adolescents between 1 and 16 years of old with kidney stone - On ultrasound, kidney stones are larger than or equal to 5 mm - Without any history of recent urinary tract infection - Have normal kidney function - Without urinary tract anomalies
Exclusion criteria:
- A child who needs urological intervention during the project. - A child who stops taking medication due to illness such as diarrhea, etc. - Any patient who does not want to continue the project.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **25**
any child with kidney stone
Randomization (investigator's opinion)
Randomized
Randomization description
Using a table of random numbers
Blinding (investigator's opinion)
Single blinded
Blinding description
Data analysis is performed by a person who does not know the type of drug prescribed to the patient (solution or sachet).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urology nephrology research center
Street address
Pasdaran ave
City
Tehran
Province
Tehran
Postal code
1666663111
Approval date
2020-10-22, 1399/08/01
Ethics committee reference number
IR.SBMU.UNRC.REC.1399.017

Health conditions studied

1

Description of health condition studied
kidney stone
ICD-10 code
Z00.6
ICD-10 code description
Encounter for examination for normal comparison and control in clinical research program

Primary outcomes

1

Description
kidney stone size
Timepoint
initiation and three later after the study
Method of measurement
Ultrasound

2

Description
Urinary pH
Timepoint
First, one month and three months later
Method of measurement
pH meter

3

Description
24-hour urine citrate
Timepoint
initiation and three later after the study
Method of measurement
Enzymatic evaluation

Secondary outcomes

1

Description
compliance
Timepoint
Three months later
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: treatment with Polycitra-K solution
Category
Treatment - Drugs

2

Description
Intervention group: treatment with Polycitra-K sachet
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid hospital
Full name of responsible person
Dr Masume Mohkam
Street address
shariati
City
Tehran
Province
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Postal code
1546815514
Phone
+98 21 2256 7222
Email
mohkam@sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Ali-asghar pediatric hospital
Full name of responsible person
Dr Nakisa Hooman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Abbas Basiri
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Abbas basiri
Position
Head of urology nephrology research center
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Shahid Beheshti University of Medical Sciences
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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
Not applicable
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
Article
When the data will become available and for how long
6 months after published
To whom data/document is available
All researchers
Under which criteria data/document could be used
In order to citation OR using in review articles
From where data/document is obtainable
Authors e-mail OR UNRC data registry
What processes are involved for a request to access data/document
Request e-mail to authors OR research manager of UNRC
Comments
None