Effectiveness of potassium citrate solution in renal microlithiasis treatment in 1 month to 15 years old children

Protocol summary

Study aim
Determination of the effectiveness of potassium citrate solution in the treatment of renal microlithiasis in children one month to 15 years old

Design
A phase 3 clinical trial with one intervention group and one control group as parallel groups, simple randomized by coded card selection, and a sample size of 60

Settings and conduct
In this study, 60 children between the ages of 1 month and 15 years referred to Hajar Hospital in Shahrekord who have microlithiasis less than 3 mm in sonography will randomly be divided into 2 groups by selecting a card. In the first group of children, only conservative and protective measures such as breast milk consumption, prevention of dehydration and less salt consumption will be recommended, and in the second group, in addition to supportive measures, they will be treated with potassium citrate solution for 3 months. Then, to evaluate the presence or absence, size and number of stones, patients in both groups will be examined and compared with sonography after 3 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children aged 1 month to 15 years with kidney stones less than 3 mm and parental consent to participate in the study; Exclusion criteria: renal hydronephrosis, multiple stones, urinary reflux, recurrent urinary tract infection

Intervention groups
In one group of children, only conservative and supportive measures such as breastfeeding, dehydration prevention and less salt intake will be recommended, and in the other group, in addition to supportive measures, they will be treated with potassium citrate solution (Combination of 22% potassium citrate powder and 68.8% acetic acid from Merck factory in Germany with distilled water) for 3 months.

Main outcome variables
Number of stones; Size of stones
Scientific title
Effectiveness of potassium citrate solution in renal microlithiasis treatment in 1 month to 15 years old children

Public title
Effect of potassium citrate solution in the treatment of renal microlithiasis in children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 1 month to 15 years with kidney stones less than 3 mm Patient parents' satisfaction with participating in the study

Exclusion criteria:
Renal hydronephrosis Numerous stones Urinary reflux Recurrent urinary tract infections

Age
From 1 month old to 15 years old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 60
Actual sample size reached: 60

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomize the study, simple randomization with individual unit is used, so that patients randomly select one of the cards containing the codes A or B so they enter one of the two treatment groups.

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 Shahrekord University of Medical Sciences

Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713492

Approval date
2020-06-07, 1399/03/18

Ethics committee reference number
IR.SKUMS.REC.1399.084

Health conditions studied

1

Description of health condition studied
Renal microlithiasis

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Number of stones

Timepoint
At the beginning of the study and 3 months after the start of the study

Method of measurement
Sonography

Secondary outcomes
empty

Intervention groups

1

Description
Control group: In this group, children and their parents will only be advised to take conservative and supportive measures such as breast milk consumption, prevention of dehydration and less salt consumption for 3 months.

Category
Treatment - Other

2

Description
Intervention group: In addition to supportive measures,
treated with potassium citrate solution (combination of 22% potassium citrate powder and 68.8% acetic acid from the German Merck factory with distilled water that prepared in one center and by one person) for 3 months.

Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Hajar Hospital
Full name of responsible person
Saeed Mohajeri
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Hajar Hospital, Nursing Street, Kashan Blvd, Shahrekord City, Chahar Mahal and Bakhtiari Province
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public

Domestic or foreign origin
Domestic

Country of origin
empty

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
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Position
Assistant Professor
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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