

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N40**

Registration date: **2020-10-25, 1399/08/04**

Registration timing: **retrospective**

Last update: **2020-10-25, 1399/08/04**

Update count: **0**

Registration date

2020-10-25, 1399/08/04

Registrant information

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-22, 1398/11/02

Expected recruitment end date

2020-06-25, 1399/04/05

Actual recruitment start date

2020-03-25, 1399/01/06

Actual recruitment end date

2020-08-31, 1399/06/10

Trial completion date

2020-08-31, 1399/06/10

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

2

Description

Stone size

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

Street address

Hajar Hospital, Nursing Street ,Kashan Blvd,
Shahrekord City, Chahar Mahal and Bakhtiari

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dr.saedmohajeri@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

Vice chancellor for research, Building No. 2,
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Mehr.sadeghi1ir@gmail.com

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

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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Saeed Mohajeri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

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Latest degree

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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