Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Comparing Effectiveness of combination of magnesium oxide and potassium citrate with potassium citrate in children with urolithiasis

Protocol summary

Summary

(1) Objectives: Comparing effectiveness of combination of magnesium oxide and potassium Polycitra with potassium Polycitra in children with urolithiasis. (2) Design: Patients will randomly be divided into intervention and control groups. Urinary and serum samples will be obtained and patients will receive treatment for three months. After three months, patients will be re-evaluated by sonography and biochemistry tests. (3) Setting and conduct: A random morning urine sample will be obtained in order to measure urinary citrate, uric acid and oxalate and a serum sample will be obtained in order to measure blood gases and serum calcium, creatinine, sodium, potassium and magnesium. Also, magnesium urinary level and urine specific gravity and pH will be checked at the beginning of study and at the time of radiological re-evaluation. (4) Participants including major eligibility criteria: All children with completed informed consent form and with diagnosis of urinary tract stone larger than 2 millimeter diameter will be included in the study. (5) Intervention: In the control group, patients will receive 1-2 cc/kg potassium Polycitra (220 grams potassium citrate and 66 grams citric acid which solute in 1000 cc distilled water; contain 2 mEq/cc potassium) divided into three doses and in intervention group, patients will receive daily single dose of magnesium oxide with recommended dietary allowance (RDA) in relation to patient's age and sex (30 to 410 mg/kg) and potassium Polycitra with the same dose as control group. (6) Main outcome measures (variables): Three months after initiating treatment, sonograpgy will be conducted on patients and they will be evaluated in terms of stone size changes (at least 1 mm) or stone resolution. Also a urine sample will be obtained to assess urine specific gravidity, pH, magnesium, calcium and creatinine in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041217234N1**
Registration date: **2014-12-22, 1393/10/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-22, 1393/10/01

Registrant information

Name
Nayereh Tousi
Name of organization / entity
Mashhad University of Medical Science
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing Effectiveness of combination of magnesium oxide and potassium citrate with potassium citrate in children with urolithiasis

Public title
Comparing Effectiveness of combination of magnesium oxide and potassium citrate with potassium citrate in children with urolithiasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: All children: 1. Under 15 years of age with sonographic diagnosis of stone. 2. With stones greater than 2 mm diameter; Microlithiasis below 2 mm due to the possible technical errors and less clinical value will be ignored. 3. Who completed informed consent form. Exclusion criteria: 1. Presence of side effects (such as gastritis, gastrointestinal complications due to potassium citrate, sluggishness, lethargy, muscle weakness and diarrhea due to magnesium which drug would be discontinued in this case) 2. Comorbidities which influence tubular secretion such as renal tubular acidosis, pyelonephritis and obstructive uropathy. 3. Not referring in order to sonography and laboratory tests 4. Diagnosed cases who are under medication therapy 5. Over 15 years old age 6. Stones with 2 mm diameter or less 7. Patients need treatment other than conventional therapies such as patients who need hydrochlorothiazide or cystinuria patients who need penicillamine.

Age
To **14 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Mashhad University of Medical Sciences

Street address
Danshgah St, Mashhad, Khorasan Razavi, Iran.

City
Mashhad

Postal code

Approval date
2013-12-21, 1392/09/30

Ethics committee reference number
920636

Health conditions studied

1

Description of health condition studied
nephrolythiasis

ICD-10 code
n20

ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
At least 1 millimeter change in stone size during treatment

Timepoint
First day and end of third month

Method of measurement
Sonography

Secondary outcomes

1

Description
Drug side effects such as gastritis and other GI complications due to potassium citrate and muscle weakness due to magnesium

Timepoint
Any time during study

Method of measurement
History and physical examination

Intervention groups

1

Description
In intervention group, patients will receive daily single dose of magnesium oxide with recommended dietary allowance (RDA) in relation to patient's age and sex (30 to 410 mg/kg) and 1-2 cc/kg potassium Polycitra (220 grams potassium citrate and 66 grams citric acid which solute in 1000 cc distilled water; contain 2 mEq/cc potassium) divided into three doses for three months.

Category

Treatment - Drugs

2

Description
In the control group, patients will receive 1-2 cc/kg potassium Polycitra (220 grams potassium citrate and 66 grams citric acid which solute in 1000 cc distilled water; contain 2 mEq/cc potassium) divided into three doses for three months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr Sheikh Hospital, Pediatric Nephrology Department

Full name of responsible person
Nayereh Tousi

Street address
Dr Sheikh Hospital, Tohid Square, Motahari Avenue, Mashhad, Khorasan Razavi, Iran

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Daneshgah Street, Mashhad, Khorasan Razavi, Iran

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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
Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Science

Full name of responsible person
Nayereh Tousi

Position
Pediatric Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Assistant professor

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Person responsible for updating data

Contact

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Full name of responsible person
Nayereh Tousi

Position
Pediatric resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty