

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, sonography 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 gravity, 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)

Phone

+98 51 3764 6193

Email address

tousin911@mums.ac.ir

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

Contact

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Anoosh Azarfar

Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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