Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of changes in urinary parameters after oral administration of magnesium chlorides and potassium citrate in pediatric with calcium oxalate urolithiasis.

Protocol summary

Summary

The objective of the present study is to investigate changes in urinary parameters after oral administration of magnesium chlorides and potassium citrate in pediatrics with calcium oxalate urolithiasis. In this interventional, semi-experimental, and prospective study, 30 patients, aged 1-18 years old, for whom the urinary tract stone diagnosis confirmed by the clinical symptoms or ultrasonography by a specialist, will be recruited. The patients will receive the potassium citrate solution for 4 weeks as the first phase and then solution of potassium citrate and chloride magnesium for another 4 weeks as the second phase. A sample of 24-hour urine and blood sample will be taken and calcium, potassium, Na, Cl, citrate, oxalate, Phosphate, creatinine, and magnesium will be checked before the study and after each phase and the results compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707091282N1**
Registration date: **2011-04-12, 1390/01/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-12, 1390/01/23

Registrant information

Name

Alaleh Gheissari

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences and Health Services

Expected recruitment start date

2008-02-02, 1386/11/13

Expected recruitment end date

2011-01-01, 1389/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of changes in urinary parameters after oral administration of magnesium chlorides and potassium citrate in pediatric with calcium oxalate urolithiasis.

Public title

Evaluation of changes in urinary parameters after oral administration of magnesium chlorides and potassium citrate in pediatric with calcium oxalate urolithiasis.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 2-12 years with possibility of calcium oxalate kidney stone, No past history of peptic ulcer, chronic diarrhea or cardiac disease, primary hyperparathyroidism, consumption of anticonvulsants,

No proven history of disorders affecting tubular ion excretion such as: recent urinary tract infection , distal renal tubular acidosis , chronic pyelonephritis, renal dysfunction and obstructive uropathy Exclusion criteria: Patients who did not complete all steps of the study, refusing to consume either potassium citrate or magnesium chloride

Age

From **2 years** old to **18 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences and Health Services

Street address

Isfahan University of Medical Sciences, Hezarjarib St., Isfahan

City

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Postal code

Approval date

2008-08-20, 1387/05/30

Ethics committee reference number

286004

Health conditions studied

1

Description of health condition studied

urolithiasis

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Urine parameter (Ca-K-Na-Cl-Cit-Ox-P-Cr-Mg)

Timepoint

Before and4 weeks after intervention

Method of measurement

24-hour urine test

2

Description

Blood parameter (Ca-K-Na-Cl-Cit-Ox-P-Cr-Mg)

Timepoint

Before and 4 weeks after intervention

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Phase 1: Oral solution of potassium citrate, 0.5 cc/kg/dose, every 8 hours, 30 min after meal, for 4 weeks

Category

Treatment - Drugs

2

Description

Phase 2: Combination of K Citrate 0.5 cc/kg/dose, every 8 hours, 30 min after meal as well as Mg Chloride 10-20 mg/kg/dose equivalent to 180 meq elemental Mg for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences

Full name of responsible person

Street address

Isfahan University of Medical Sciences, Hezarjarib St., Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences and Health Services
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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
Isfahan University of Medical Sciences and Health Services
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

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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