

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of potassium citrate in treatment of 2 - 7mm diameter urinary tract stones in children without any metabolic or infectious risk factor of nephrolithiasis

Protocol summary

Summary

The aim of our study was assessment of effect of potassium citrate therapy on pediatric nephrolithiasis. All less than 16 years old patients with a history of kidney stone with 2-7 mm diameter on kidney ultrasonography will be enrolled in study. Stone is defined as an opacity with more than 2 mm diameter and posterior shadow on kidney ultrasound. All patients will be evaluated for metabolic and infectious risk factors of renal stone formation. Patients with 2-7mm diameter stones and no such risk factors will be enrolled in study. The exclusion criteria is urinary tract infection, renal failure, surgical or lithotripsy intervention and incomplete follow up. Patients would put on two groups; group 1 patients were treated with 1-2ml/kg potassium citrate daily and group 2 patients received no drug. The supportive therapy was performed for all patients in two groups. The follow up by serial ultrasound was done every 3 months. The efficacy of therapy was assessed as the reduction in the number, maximum stone size and total stone burden. The response of therapy is defined as 5 grade ; worst, no change, less than 50% improvement, 50% or more improvement and cure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122420419N2**
Registration date: **2017-07-14, 1396/04/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-14, 1396/04/23

Registrant information

Name

Hamid Mohammadjafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3331 3866

Email address

hmjafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of medical sciences

Expected recruitment start date

2015-10-19, 1394/07/27

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of potassium citrate in treatment of 2 - 7mm diameter urinary tract stones in children without any metabolic or infectious risk factor of nephrolithiasis

Public title

The efficacy of potassium citrate in children with nephrolithiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All less than 16 years old patients with a history of kidney stone with 2-7 mm diameter on kidney ultrasonography without any infectious or metabolic risk factors including hypercalciuria, uricosuria, cystinuria, hyperoxaluria and hypocitraturia. Exclusion criteria: urinary tract infection: renal failure: surgical or lithotripsy intervention : incomplete follow up.

Age

From **2 months** old to **16 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The patients put in one of two groups serially.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for research of Mazandaran University of Medical Sciences, Moalem square, sar

City

Sari

Postal code

4818856361

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

IR.MAZUMS.REC.94-1423

Health conditions studied

1

Description of health condition studied

Nephrolithiasis

ICD-10 code

N20

ICD-10 code description

Nephrolithiasis NOS Renal calculus or stone Staghorn calculus Stone in kidney

Primary outcomes

1

Description

Stone number

Timepoint

Before and 3 and 6 months after intervention

Method of measurement

Alteration in stone number after intervention as millimeter on kidney sonography

2

Description

Total stone mass

Timepoint

Before and 3 and 6 months after intervention

Method of measurement

Alteration in sum of all stones size after intervention as millimeter on kidney sonography

3

Description

stone size

Timepoint

Before and 3 and 6 months after intervention

Method of measurement

Alteration in stone size after intervention as millimeter on kidney sonography

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group 1: Potassium citrate 1-2 ml/kg/ day in 2-3 divided doses. The drug will be provided by pharmacy faculty of Mazandaran university of medical sciences.

Category

Treatment - Drugs

2

Description

Control group: No intervention and no drug for treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali

Full name of responsible person

Hamid Mohammadjafari

Street address

Pediatric ward, Booali hospital, Pasdaran Avenue, Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmadali Enayati

Street address

Vice Chancellor for research of Mazandaran University of Medical Sciences, Moalem square, sari

City

sari

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 of Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Zahra Tahernassab

Position

GP

Other areas of specialty/work

Street address

Pediatric Ward, booali hospital, Passdaran avenue, Sari

City

sari

Postal code

Phone

+98 11 3334 3018

Fax

Email

hamidmj46@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hamid Mohammadjafari

Position

subspecialist

Other areas of specialty/work

Street address

Pediatric ward, Boali hospital, Passdaran Street, Sari

City

sari

Postal code

4818856361

Phone

+98 11 3334 3018

Fax

Email

hamidmjaafari@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of medical sciences

Full name of responsible person

Hamid Mohammadjafari

Position

professor

Other areas of specialty/work

Street address

Pediatric ward, Boali hospital, passdaran Avenue, Sari

City

Sari

Postal code

4818856361

Phone

+98 33313866

Fax

+98 11 3334 3506

Email

hamidmjafari@yahoo.com

Web page address

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