Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Evaluating the effect of atorvastatin on metabolic abnormalities, Tubular injury and oxidative stress in recurrent calcium stone patients.

Protocol summary

Summary

Ultimate Goal: Evaluating the effect of atorvastatin on metabolic abnormalities, tubular injury and oxidative stress in recurrent calcium stone patients. Specific Objectives: 1. Evaluating the effect of atorvastatin on urine Malondialdehyde, as oxidative stress index, and neutrophil gelatinase-associated lipocalin, as tubular injury index, in recurrent calcium stone patients. 2. Evaluating the effect of atorvastatin on morning urine pH and 24-hour urine oxalate, calcium, magnesium, creatinine, sodium, potassium, citrate, calcium oxalate relative supersaturation (RSS), calcium phosphate RSS and uric acid RSS in recurrent calcium stone patients. Study Design: Pilot double-blinded randomized clinical trial. Study Population: Recurrent stone forming patients with hyperoxaluria, recruited from the nephrolithiasis prevention clinic at Labbafinejad Hospital. Study groups: Two groups receiving either Atorvastatin (20 mg per day) or placebo, for 3 months. Sample size: 15 patients will be recruited in each group because of the pilot design of the study. Patients will be randomly divided between the groups. Study variable: Main variables: oxidative stress index (Malondialdehyde) and tubular injury index (neutrophil gelatinase-associated lipocalin). Secondary variables: Morning urine pH, 24-hour urine oxalate, calcium, magnesium, creatinine, sodium, potassium, citrate, calcium oxalate RSS, calcium phosphate RSS and uric acid RSS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021826406N2**
Registration date: **2017-06-17, 1396/03/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-17, 1396/03/27

Registrant information

Name

Sanaz Tavasoli

Name of organization / entity

Urology and Nephrology Research Center,Shahid Beheshti University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of atorvastatin on metabolic abnormalities, Tubular injury and oxidative stress in recurrent calcium stone patients.

Public title

Evaluating the effect of atorvastatin on kidney stone.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: History of calcium kidney stone (stone should be radio-opaque in radiological evaluation); at least 2 times of kidney stone episodes (Recurrent stone); at least 20 days since the last treatment; age 18 to 65 years; Hyperoxaluria (24-hour urine oxalate over 40 and less than 80 mg); willingness to cooperate in the study. Exclusion criteria: Primary or enteric hyperoxaluria (urine oxalate>80 mg/24h);taking any drugs or supplements with antioxidant or anti-inflammatory effects (e.g. steroids, Nonsteroidal Antiinflammatory Drugs, pioglitazone, ...), multivitamins containing vitamin A,C or E and any supplement containing anti-oxidants; History of diabetes mellitus, hepatic failure, thyroid or parathyroid diseases, cancers or immunologic diseases, chronic kidney disease (Glomerular filtration rate< 60), Urinary tract infection and chronic diarrhea; Pregnancy or lactation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will be randomly divided between two groups (using a block randomization design) and will receive three months of drug or placebo accordingly. In order to make the study double blind, one of the project colleagues will code the drugs or placebo and the codes will be kept until the end of the study analyses. The drugs and placebo will be identical and principal investigators who will carry out sampling and testing will be unaware until the end of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urology and Nephrology research center, Shahid Beheshti University of Medical Sc

Street address

N0. 103 - 9th Boostan St., Pasdaran St.

City

Tehran

Postal code

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

931223-10

Health conditions studied

1

Description of health condition studied

Calcium kidney stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Urine malondialdehyde

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

colorimetric method using Thiobarbituric acid

2

Description

Urine neutrophil gelatinase-associated lipocalin

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Morning urine pH

Timepoint

Before the intervention,3 months after the intervention

Method of measurement

Dip stick

2

Description

24 hour urine volume

Timepoint

Before the intervention,3 months after the intervention

Method of measurement

observation

3

Description
24 hour urine creatinine
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
Colorimetric

4

Description
24 hour urine calcium
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
Colorimetric

5

Description
24 hour urine oxalate
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
Assay kit with Enzymatic method

6

Description
24 hour urine phosphorus
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
Colorimetric

7

Description
24 hour urine magnesium
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
Colorimetric

8

Description
24 hour urine citrate
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
Assay kit with Enzymatic method

9

Description
24 hour urine uric acid
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
Colorimetric

10

Description
24 hour urine sodium
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
flame photometry or indirect ion selective electrode

11

Description
24 hour urine potassium
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
flame photometry or indirect ion selective electrode

12

Description
24 hour urine chloride
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
flame photometry or indirect ion selective electrode

13

Description
Calcium oxalate relative supersaturation
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
calculation by lithorisk software

14

Description
Calcium phosphate relative supersaturation
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
calculation by lithorisk software

15

Description
Uric acid relative supersaturation
Timepoint
Before the intervention,3 months after the intervention
Method of measurement
calculation by lithorisk software

Intervention groups

1

Description
Intervention group: Patients taking atorvastatin oral tab (20 mg). Duration and Dosage: One daily for 3 month.
Category
Treatment - Drugs

2

Description
Control group: Patients taking placebo. Duration and Dosage: One daily for 3 month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Stone prevention clinic- Labafinejad hospital - Urology and Nephrology Research Center
Full name of responsible person
Sanaz Tavasoli
Street address
No 103, 9th Boustan St., Pasdaran Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shabnam Golshan
Street address
No 103, 9th Boustan St., Pasdaran Ave.
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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
Urology and Nephrology Research Center, Shahid Beheshti 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

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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