Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluating the effect of a probiotic supplement including Lactobacillus and Bifidiobacterium (with emphasis on the strains of Lactobacillus acidophilus LA14 and NCFM, Lactobacillus gasseri and Bifidiobacterium lactis BI07) on 24 hour urine oxalate and calcium oxalate supersaturation in recurrent calcium stone patients with hyperoxaluria: a randomized clinical trial

Protocol summary

Summary

Objectives :Determine the effect of a probiotic supplement including Lactobacillus and Bifidiobacterium (with emphasis on the strains of Lactobacillus acidophilus LA14 and NCFM, Lactobacillus gasseri and Bifidiobacterium lactis BI07) on 24 hour urine oxalate and calcium oxalate supersaturation in recurrent calcium stone patients with hyperoxaluria Design: Double blind Randomized Clinical trial (blinded for patients and researchers) Setting and conduct: 1- Evaluation of the ability to degrade oxalate in strains listed in title plus available species (including lactobacillus and Bifidobacterium spp.) and selection of best strains 2- Preparation of a probiotic supplement from selected strains 3- Patient enrollment and assessment of 24-hour urine oxalate and supersaturation of calcium oxalate, examining stool samples by real time PCR to investigate the colonization of selected bacteria, assessment of fecal oxalate (sample size: 55 patients in each group) 4- Intervention (4 weeks) 5- Repeat step 3 6- 4-week washout 7- Repeat step 3 for final assessment Major Inclusion and Exclusion criteria Inclusion criteria: Recurrent calcium stone former; Age 18-65 years; Hyperoxaluria (24 h urine oxalate >40 mg/24h) Exclusion criteria: Primary or enteric hyperoxaluria (urine oxalate>80 mg/24h); Taking any drugs which affect 24 hour urine calcium, oxalate or supersaturation; History of any confounding chronic disease including and Urinary tract infection Intervention: Consuming probiotic supplement or placebo Main outcome measures (variables): 24 hour urine oxalate and calcium oxalate supersaturation

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016020626406N1**
Registration date: **2016-06-15, 1395/03/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-06-15, 1395/03/26

Registrant information

Name

Sanaz Tavasoli

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 7222

Email address

s.tavasoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

1- National Institute for medical research development 2- Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of a probiotic supplement including Lactobacillus and Bifidiobacterium (with emphasis on the strains of Lactobacillus acidophilus LA14 and NCFM, Lactobacillus gasseri and Bifidiobacterium lactis BI07) on 24 hour urine oxalate and calcium oxalate supersaturation in recurrent calcium stone patients with hyperoxaluria: a randomized clinical trial

Public title

A clinical trial to investigate the effects of probiotic supplementation on the amount of urine oxalate in patients with recurrent calcium kidney stones

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with a history of at least 2 times of calcium (radiopaque) kidney stone episodes in recent 25 months (Recurrent stone former); at least 20 days since the last treatment they have; at least 3 months since following general dietary advice on recurrence prevention (drinking advice, high oxalate food restriction, animal protein restriction, fruit and vegetable intake encouragement, salt restriction and fat intake modification); 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 which affects calcium metabolism, including thiazides; Taking any drugs which affects oxalate metabolism or calcium oxalate supersaturation, including vitamin B6; History of diabetes mellitus, hepatic failure, thyroid or parathyroid diseases, chronic kiodney disease (CKD), Urinary tract infection (UTI), chronic diarrhea or immunologic diseases; 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: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

1- Preparation of strains listed in title plus available species (including lactobacillus and Bifidobacterium spp.) 2- Evaluation of the ability to degrade oxalate (before and after treatment of strains with oxalate in order to increase the expression of oxalate degrading enzymes) and selection of best conditions for the treatment of strains 3- Preparation of a probiotic supplement from selected strains Randomization method: Blocked randomization

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

No 103, 9th Boustan St., Pasdaran Ave

City

Tehran

Postal code

Approval date

2016-06-07, 1395/03/18

Ethics committee reference number

IR.SBMU.UNRC.1395.3

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

24 hour urine oxalate

Timepoint

Before the intervention, 4 weeks after the intervention, 8 weeks after intervention

Method of measurement

Enzymatic method

2

Description
Calcium oxalate supersaturation
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after intervention
Method of measurement
Calculation by LITHORISK software

Secondary outcomes

1

Description
Stool oxalate
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after intervention
Method of measurement
Enzymatic method

2

Description
Stool lactobacillus count
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after intervention
Method of measurement
real-time PCR

3

Description
Stool bifidobacter count
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after intervention
Method of measurement
real-time PCR

Intervention groups

1

Description
Intervention group: Patients taking probiotic supplement made from strains selected in the study. Place of supplement production: Iranian society of probiotic and functional foods. Duration and Dosage: One daily for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients taking placebo. Place of placebo production: Iranian society of probiotic and functional foods. Duration and Dosage: One daily for 4 weeks
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
National Institute for Medical Research Developement
Full name of responsible person
Non-communicable diseases commitee
Street address
Between Gharib and Eskandari St., Azadi Ave.
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Institute for Medical Research Developement
Proportion provided by this source
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

2

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

Proportion provided by this source

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

Urology and Nephrology Research Center

Full name of responsible person

Sanaz Tavasoli

Position

Assistant Professor

Other areas of specialty/work

Street address

No 103, 9th Boustan. St., Pasdaran Ave.

City

Tehran

Postal code

Phone

+98 21 2256 7222

Fax

Email

s.tavasoli@sbmu.ac.ir; sanaz.tavasoli@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urology and Nephrology Research Center

Full name of responsible person

Sanaz Tavasoli

Position

Associate Professor

Other areas of specialty/work

Street address

No 103, 9th Boustan St., Pasdaran Ave.

City

Tehran

Postal code

Phone

+98 21 2256 7222

Fax

Email

s.tavasoli@sbmu.ac.ir; sanaz.tavasoli@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Urology and Nephrology Research Center

Full name of responsible person

Sanaz Tavasoli

Position

Associate Professor

Other areas of specialty/work

Street address

No 103, 9th Boustan St., Pasdaran Ave.

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Postal code

Phone

+98 21 2256 7222

Fax

Email

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