Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

To study the efficacy of Extended-release Urocitra on urinary pH and 24-hour urine citrate in patients with observing the intact pills in feces without chronic diarrhea

Protocol summary

Study aim

To study the efficacy of Extended-release Urocitra on urinary pH and 24-hour urine citrate in patients with observing the intact pills in feces without chronic diarrhea

Design

This clinical trial (quasi experimental), rhse 3, 30 patients, 15 with and 15 without previous observing Extended-release Urocitra intact pills in feces included in the study. All the patients recieved the same treatment, so the randomization is not possible.

Settings and conduct

- Complete questionnaire regarding complete physical exam, measuring fresh urine pH, serum and 24-hour urine metabolite analysis at beginning the study - the patients in both group will treat with Extended-release Urocitra (Sobhan darou Co.) 10 mg/ TDS till to 4 weeks. - measuring fresh urine pH 2 weeks after the trial - measuring fresh urine pH and reassess serum and 24-hour urine metabolite analysis at the end of the study (4 weeks after using pill)

Participants/Inclusion and exclusion criteria

Patients with kidney stone, between 18 and 65 years of old, without evidence of using Extended-release Urocitra during two weeks ago, without history of chronic diarrhea or chronic kidney diseases (stage 3&4), no pregnancy or lactation

Intervention groups

-Intervention group: Patients with previous observing intact pills of Extended-Release Urocitra 10 meq in feces - Control group: Patients without previous observing intact pills of Extended-Release Urocitra 10 meq in feces

Main outcome variables

fresh urine pH; 24-hour urine citrate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045244N4**
Registration date: **2022-08-17, 1401/05/26**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-17, 1401/05/26**
Update count: **0**

Registration date

2022-08-17, 1401/05/26

Registrant information

Name

Maryam Taheri

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

taheri233@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
To study the efficacy of Extended-release Urocitra on urinary pH and 24-hour urine citrate in patients with observing the intact pills in feces without chronic diarrhea

Public title
To study the efficacy of extended-release Urocitra in patients with observing intact pills in feces

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Urolithiasis patients with and without observing extended release Urocitra in feces
Exclusion criteria:
chronic kidney disease (stage 3&4) pregnancy or lactation

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **3**
The intervention group are urolithiasis patients with previous observing Extended-release Urocitra in feces. Therefore it is not possible to calculate the sample size, exactly. Available patients will include in the trial.

Randomization (investigator's opinion)
N/A

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
urology nephrology research center
Street address
Pasdaran
City
Tehran
Province
Tehran
Postal code
1666663111

Approval date
2022-01-27, 1400/11/07

Ethics committee reference number
IR.SBMU.UNRC.REC.1400.016

Health conditions studied

1

Description of health condition studied
Renal stone

ICD-10 code
Z00.6

ICD-10 code description
Encounter for examination for normal comparison and control in clinical research program

Primary outcomes

1

Description
24-hour urine citrate

Timepoint
after 4 weeks treatment with Extended-release Urocitra

Method of measurement
24- hour urine citrat measurment (enzymatic), mg/day

2

Description
Urine pH

Timepoint
after 4 weeks treatment with Extended-release Urocitra

Method of measurement
Measurement of fresh urine pH by pH meter

3

Description
Investigation of the possibility of recurrence of observing intact pills in the feces of patients with previous proclem

Timepoint
After four weeks

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with prevous history of observing the intact pills of Extended-release Urocitra in feces (without chronic diarrhea), will treated by potassium citrate extended-release, 10 mg, TDS, produced by Sobhan daru company, under brand of Urocitra-ER, for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients without prevous history of observing the intact pills of Extended-release Urocitra in feces (without chronic diarrhea), will treated by potassium citrate extended-release, 10 mg, TDS, produced by Sobhan daru company, under brand of Urocitra-ER, for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

urology nephrology research center

Full name of responsible person

Abbas Basiri

Street address

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sobhan darou Co

Full name of responsible person

Ali Mortazavi

Street address

west Fatemi

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Province

Tehran

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1411853695

Phone

+98 21 6656 8181

Email

info@sobhandarou.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Cooperation contract for the implementation of a research project entitled To study the efficacy of Extended-release Urocitra on urinary pH and 24-hour urine citrate in patients with observing the intact pills in feces without chronic diarrhea

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abbas Basiri

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Taheri

Position

Assisstant professor

Latest degree

Specialist

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The results and data will be available.

When the data will become available and for how long
6 months after the published related article

To whom data/document is available
Valid academic centers or valid academic persons

Under which criteria data/document could be used
In order to citation, using in the same trials, studies or review articles

From where data/document is obtainable
UNRC data registry affiliated to Shahid Beheshti University of Medical sciences

What processes are involved for a request to access data/document
requet form via email or another valid correspondence

Comments
No comment