

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 proplem

Timepoint

After four weeks

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with previous 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 previous 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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sobhan darou Co

Full name of responsible person

Ali Mortazavi

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west Fatemi

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1411853695

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Maryam Taheri

Position

Assistant professor

Latest degree

Specialist
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Person responsible for updating data

Contact
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Shahid Beheshti University of Medical Sciences
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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

request form via email or another valid correspondence

Comments

No comment