Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effects of Portulaca Oleracea extract on thirsty and 24 hour urine indices in patients with renal stone: a double-blind randomized placebo-controlled clinical trial

Protocol summary

Study aim
The effects of Portulaca Oleracea extract on thirsty and 24 hour urine indices in patients with renal stone

Design
Clinical trials with controlled group , double blind, randomized clinical trials. sample size : 60 ; Randomization : Balanced block Randomization

Settings and conduct
Patients are randomly allocated into two experimental groups. In the group 1, the patients received Portulaca Oleracea powder and standard treatment of stone based on urine metabolic evaluation (8 weeks) . The group 2 receive Placebo (admixing 2 g of starch powder and 0.5 g brown sugar) and standard treatment of stone based on urine metabolic evaluation for 8 weeks . 24 h urine collection and Blood samples are drawn in 2steps. Study will be executed at Tehran Shahid modarres hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age 18-65 years and Literate , history of renal stone Non-inclusion criteria: Patients with diabetes , Oral problems ,No use of angiotensin II inhibitors and Patients with colds

Intervention groups
The intervention group (n = 30) received Portulaca Oleracea extract and standard treatment of stone based on urine metabolic evaluation for 8 weeks . .The control group (n = 30) received theplacebo and standard treatment of stone based on urine metabolic evaluation for 8 weeks .

Main outcome variables
Serum sodium level, Serum potassium level, Total antioxidant; Blood creatinine, Blood urea, Serum uric acid, 24-hour uric acid; 24-hour urine citrate; , The degree of thirst.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170725035305N4**
Registration date: **2020-05-02, 1399/02/13**
Registration timing: **prospective**

Last update: **2020-05-02, 1399/02/13**
Update count: **0**

Registration date
2020-05-02, 1399/02/13

Registrant information

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Amirhesam Alirezaei
Name of organization / entity
Shahid Beheshti University of Medical Sciences and Health Services
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of Portulaca Oleracea extract on thirsty and 24 hour urine indices in patients with renal stone: a double-blind randomized placebo-controlled clinical trial

Public title
The effects of Portulaca Oleracea extract on thirsty and 24 hour urine indices

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-65 years Literate
Exclusion criteria:
Patients with diabetes Oral problems No use of angiotensin II inhibitors Patients with colds

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of balanced block randomization used with a block size of 4. For the allocation sequence, we applied computer-generated by random numbers. Medicines containing Oleracea extract or placebos with the same shape and color numbered with a code in sealed envelopes. Each coded prepared medication with a label by one number from 1 to 60. The patients allocated into two groups: group 1(n=30) received Oleracea extract, and group2 (n=30) received placebo . Both groups were identical in terms of characteristics and comorbid conditions; the participants divided sequentially.The control group is assigned to "A" and the intervention group to "B", and then the two groups are divided into 6 blocks: (1) AAB, (2) B A A, (3 (B), b), b), b), b), b), b) These blocks are randomly put together by computer and provide a chain of randomized groups (eg: B A B B A B B A B B A B B). Then the patients enter these groups in order of entry.

Blinding (investigator's opinion)
Double blinded

Blinding description
During study period ,a nurse coordinated the study and registered the study codes and the nurse handed the labeled drugs over participants and collected all the data. The patients , investigators , laboratory staffs and supervisers all were blinded to treatment assignment and lab data measurements during the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid beheshti University of Medical Sciences

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7th Floor, Bldg No.2 , Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, chamran highway,Tehran, Iran.

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19839-63113

Approval date
2019-09-16, 1398/06/25

Ethics committee reference number
IR.SBMU.MSP.REC.1398.538

Health conditions studied

1

Description of health condition studied
Patients with kidney stones

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
serum Potassium level

Timepoint
At the start of the study and at the end of the study

Method of measurement
blood sample

2

Description
serum Sodium level

Timepoint
At the start of the study and at the end of the study

Method of measurement

blood sample

3

Description
24-hour urine uric acid
Timepoint
At the start of the study and at the end of the study
Method of measurement
24 h Urine collection

4

Description
24-hour urine citrate
Timepoint
At the start of the study and at the end of the study
Method of measurement
24 h Urine collection

5

Description
Specific weight of urine
Timepoint
At the start of the study and at the end of the study
Method of measurement
Urine sample

6

Description
24 hour urine calcium
Timepoint
At the start of the study and at the end of the study
Method of measurement
24 h Urine collection

7

Description
24-hour urine creatinine
Timepoint
At the start of the study and at the end of the study
Method of measurement
24 h Urine collection

8

Description
24-hour urine Na
Timepoint
At the start of the study and at the end of the study
Method of measurement
24 h Urine collection

Secondary outcomes

1

Description
Thirst intensity
Timepoint
At the start of the study, at the end of the study
Method of measurement
using Visual Analogue Scale

2

Description
serum triglycerid level
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

3

Description
serum cholestrol level
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

4

Description
serum HDL level
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

5

Description
Total antioxidant level
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

6

Description
ESR
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

7

Description
CRP
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

8

Description
serum Uric acid level
Timepoint
At the start of the study and at the end of the study

Method of measurement
blood sample

9

Description
serum Creatinine level
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

10

Description
serum Urea level
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

11

Description
serum calcium level
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

12

Description
venous blood gas
Timepoint
At the start of the study and at the end of the study
Method of measurement
blood sample

Intervention groups

1

Description
Intervention group: The intervention group (n = 30) received a capsul containing of 2 grams Portulaca Oleracea hydro alcoholic extract and half a gram of brown sugar should be taken with 100 cc of water and standard treatment based on urine metabolic evaluation for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: The second group (30 patients) received placebo as a capsul containing of 2 grams starch powder and half a gram of brown sugar (placebo) should be taken with 100 cc of water and standard treatment based on urine metabolic evaluation for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modaress hospital of Tehran
Full name of responsible person
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Sponsors / Funding sources

1

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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
Shahid Beheshti University of Medical Sciences
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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Amirhesam Alirezaei

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Nephrology

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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
Yes - There is a plan to make this available

Title and more details about the data/document
All collected data c is an be shared after making participants unidentifiable.

When the data will become available and for how long
starting after publication

To whom data/document is available
people working in academic institutions

Under which criteria data/document could be used
Any types of analyses

From where data/document is obtainable
Email :amirhesam124@gmail.com

What processes are involved for a request to access data/document
less than 2 weeks

Comments