Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of the effect of Rudioretic supplement comparing to placebo on renal stone: A randomized clinical trial

Protocol summary

Study aim

Determining the effect of Rudioretic supplement on kidney stone expulsion

Design

160 participants (no=40 per group) are randomly assigned to 2 intervention groups (A- capsule, B- drops) and 2 placebo groups (C- capsule, D- drop) using a random digit table. Study phase 3.

Settings and conduct

This randomized controlled trial will be performed in Fayaz Bakhsh hospital. Inclusion criteria will be checked by a sonographer. Included patients will randomly be assigned to supplement and placebo groups. In the end, sonography will be repeated. Before and after 6 weeks of intervention urine biochemical test, 24h urine volume and urine pH will be determined. At last, the rate of stone expulsion will compare in two groups with SPSS 22 software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age>18, having kidney stone without hydronephrosis, No need for medication. Exclusion criteria: Pregnancy, lactation, Receiving drugs that affect kidney stones.

Intervention groups

Patients in intervention group (A) will receive 2 capsules (500 mg) of Rudioretic every 8 hours with empty stomach. Intervention group (B) will consume 40 drops of Rudioretic every 8 hours. Placebo group (C) will receive placebo capsule every 8 hours and placebo group (D) will receive 40 drops of placebo every 8 hours. Rudioretic capsule and drop contain similar amount of Zea mays, Apium graveolens, Equisetum arvense and Urtica dioica L. Placebo capsules and drop contain maltodextrin. All groups receive supplement or placebo for 6 weeks

Main outcome variables

Excreted kidney stone number

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N12**
Registration date: **2021-08-17, 1400/05/26**
Registration timing: **prospective**

Last update: **2021-08-17, 1400/05/26**
Update count: **0**

Registration date

2021-08-17, 1400/05/26

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

razeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of Rudioretic supplement comparing to placebo on renal stone: A randomized clinical trial

Public title
Rudioretic supplement and kidney stone

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosed with a kidney stone without hydronephrosis and no need for medication Age between 18-45 years Willing to participate in the study

Exclusion criteria:
Pregnancy or lactation Having known heart disease Receiving drugs that affect kidney stones

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
The Block Randomization method is used to randomize the patients. For randomization, we will visit www.sealedenvelope.com and use the randomization tab to make a list considering the number of intervention groups, sample size, block size. Block size will be 8 (AABBCCDD and other compositions). The prepared list that contains the pattern of patient allocation will be obtained and used. This site is designed in such a way that there is no limit on the number of groups for random allocation. According to the total number of samples required for the study, which is 160 patients: 40 patients in the intervention group with capsule (A), 40 patients in the intervention group with drop (B), 40 patients in the control group with capsule (C), and patients in the control group with drop. blocks will be randomly Then 160 pockets (40 pockets containing paper containing A, 40 containing B, 40 pockets containing C, and 40 pockets containing D) will be prepared based on sample size. According to a list of blocks, a trained person will be set the row of pockets. After the admission of each patient will be given a pocket and assigned to Group A (intervention 1) or B (intervention 2) or C (control group 1) or D (control group 2). The sampling process will be performed sequentially until the end of the completion of the sample size.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of research and technology deputy of Shahid Beheshti University of Medical Sciences

Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City
Tehran

Province
Tehran

Postal code
1981619573

Approval date
2019-02-17, 1397/11/28

Ethics committee reference number
IR.SBMU.RETECH.REC.1397.1304

Health conditions studied

1

Description of health condition studied
Kidney stone

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Number of excreted kidney stone

Timepoint
Start of intervention and a month later

Method of measurement
Ultrasonography and blood and urine tests

2

Description
Stone size

Timepoint
Start of intervention and a month later

Method of measurement
Sonography

Secondary outcomes

1

Description
urine volume 24 h
Timepoint
Start of intervention and a month later
Method of measurement
Urine 24 h test by BT-1500 autoanalyser

2

Description
Creatinine in urine 24h
Timepoint
Start of intervention and a month later
Method of measurement
Urine 24h test by Pars Azmoon kit

3

Description
oxalate in urine 24 h
Timepoint
Start of intervention and a month later
Method of measurement
urine 24 h test by Darmankau kit

4

Description
Citrate in urine 24 h
Timepoint
Start of intervention and a month later
Method of measurement
urine 24 h test by Darmankau kit

5

Description
Uric acid in urine 24 h
Timepoint
Start of intervention and a month later
Method of measurement
urine 24h test by Pars Azmoon kit

6

Description
Urine specific gravity
Timepoint
Start of intervention and a month later
Method of measurement
Urinalysis by BT-1500 autoanalyser

Intervention groups

1

Description
Supplement group A: will receive 2 capsules of Rudioretic every 8 hours with empty stomach for 6 weeks. Each capsule contain 500 mg of Zea mays, Apium graveolens, Equisetum arvense and Urtica dioica L.
Category
Treatment - Other

2

Description
Supplement group B: will receive 40 drops of Rudioretic every 8 hours with empty stomach for 6 weeks. Rudioretic contain Zea mays, Apium graveolens, Equisetum arvense and Urtica dioica L.
Category
Treatment - Other

3

Description
Placebo group C: will receive 2 capsules of placebo contains maltodextrine every 8 hours for 6 weeks .
Category
Placebo

4

Description
Placebo group D: will receive 40 drops of placebo contains maltodextrine every 8 hours for 6 weeks .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Fayaz Bakhsh hospital
Full name of responsible person
Soodeh Razeghi Jahromi
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
soodehrazeghi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

City
Tehran

Province
Tehran

Postal code
1981619573

Phone
+98 21 2235 7483

Email
soodehrazeghi@gmail.com

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
Soodeh Razghei Jahromi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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No. 7, West Arghavan St., Farahzadi Blv., Qods Town

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Postal code
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Phone
+98 21 2235 7483

Email
soodehrazeghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Soodeh Razghei Jahromi

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Phone
+98 21 2235 7483

Email
soodehrazeghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Soodeh Razghei Jahromi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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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 data would be available to public

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

To all

Under which criteria data/document could be used

No other critaria

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document

Sending email

Comments