

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Clinical trial on the effectiveness of Talkhab spring water on urine indices in idiopathic calcium oxalate stone former

Protocol summary

Summary

Objective: Non-randomized clinical trial on the effectiveness of Talkhab spring water in urine indices of idiopathic calcium oxalate stone former. Study population: Males aged over 18 with idiopathic calcium oxalate stone disease. Inclusion criteria: Male; history of idiopathic calcium oxalate stone formers; contraindications of supplements such as citrate, vitamin D, vitamin C, calcium, and medications; not taking too much salt; absence of any possible complications of metabolic disorders such as diabetes, hepatitis, cardiac failure; no complications of urinary tract such as hydronephrosis, nephrolithiasis, azotemia, and renal colic. Exclusion criteria: No complications of idiopathic calcium oxalate stone; no use of supplements such as citrate, vitamin D, vitamin C, calcium and medications; taking too much salt; having any possible complications of metabolic diseases such as diabetes, hepatitis, and cardiac failure; having urolithiasis such as urinary tract, nephrolithiasis, azotemia, and renal colic. Sample: Sixty samples were allocated to the intervention (n=30) and control (n=30) groups. Study intervention: Use of Talkhab spring water in patients sustaining idiopathic calcium oxalate stone. The study outcome: Urine indices and volume were evaluated before and 24 hours after the intervention. Urine calcium levels were compared in each group to determine the effect of Talkhab spring water on the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121325507N1**

Registration date: **2015-12-26, 1394/10/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-26, 1394/10/05

Registrant information

Name

Ali Serous

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Arak University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial on the effectiveness of Talkhab spring water on urine indices in idiopathic calcium oxalate stone former

Public title

Effectiveness of spring water for treatment of nephrolithiasis

Purpose

Treatment

IR.ARAKMU.REC.1394.221

Inclusion/Exclusion criteria

Inclusion criteria: Male; history of idiopathic calcium oxalate stone formers; contraindications of supplements such as citrate, vitamin D, vitamin C, calcium, and medications; not taking too much salt; absence of any possible complications of metabolic disorders such as diabetes, hepatitis, cardiac failure; no complications of urinary tract such as hydronephrosis, nephrolithiasis, azotemia, and renal colic. Exclusion criteria: No complications of idiopathic calcium oxalate stone; no use of supplements such as citrate, vitamin D, vitamin C, calcium and medications; taking too much salt; having any possible complications of metabolic diseases such as diabetes, hepatitis, and cardiac failure; having urolithiasis such as urinary tract, nephrolithiasis, azotemia, and renal colic.

Age

From **18 years** old to **90 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

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

Ethics Committee of Arak University of Medical Sciences

Street address

Vice Chancellor for Research, Arak University of Medical Sciences, A'Iam-Al-Hoda Street, Shahid Shiroodi Street

City

Arak

Postal code

3819693345

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

kidney stones

ICD-10 code

N20.0

ICD-10 code description

Stone in kidney

Primary outcomes

1

Description

Urinary indices

Timepoint

24 hours before and after use of Talkhab spring water

Method of measurement

Urinalysis

Secondary outcomes

1

Description

Urine volume

Timepoint

24 hours before and after use of Talkhab spring water

Method of measurement

Urinalysis

Intervention groups

1

Description

Intervention group: Patients with idiopathic calcium oxalate stone received Talkhab spring water on a daily basis. Measurement of urine calcium before and 24 hours after the intervention.

Category

Treatment - Drugs

2

Description

Control group: Patients with idiopathic calcium oxalate stone received natural water on a daily basis. Measurement of urine calcium before and 24 hours after the intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Ali Sirous

Street address

Valiasr Hospital- Pyrozi Avenue

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Arak University of Medical Sciences

Full name of responsible person

Ali Asghar Yaghobi

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Vice Chancellor for Research, Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

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Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Arak University of Medical Sciences

Proportion provided by this source

100

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

Arak University of Medical Sciences

Full name of responsible person

Ali Sirous

Position

Urologist

Other areas of specialty/work

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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