

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Effect of L-carnitine on the metabolites of 24-hour urine in patients with a history of recurrent stone formation.

Protocol summary

Study aim

Effect of L-carnitine on the metabolites of 24-hour urine in patients with a history of recurrent stone formation

Design

Phase 2 clinical trial, No control group, No blinding ,
Sample size of 30 patients

Settings and conduct

Place of study: Urology clinic of Golestan Hospital in Ahwaz . 24-hour urine-related markers (including calcium, oxalate, uric acid and citrate) before treatment is recorded. Patients are then followed for 2 weeks without drug treatment and on a regular diet. At the end of two weeks, the 24-hour urine is collected again and assessed for calcium, oxalate, uric acid and citrate. They are treated with only L-carnitine at a dose of 1 g daily. During the course of treatment with L-carnitine, the patients' diet was monitored for similarity to the first two weeks of follow-up. At the end of the eighth week, 24-hour urine is collected and evaluated for calcium, oxalate, uric acid, and citrate.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with a history of renal stone passage and patients undergoing surgical or non-surgical (extracorporeal shock wave lithotripsy) surgery for kidney stones or ureteral stones. Exclusion criteria include patients who first have kidney stones and patients with anatomical disorders (ureteral stenosis) , patients with endocrine disorders including hyperparathyroidism, diabetes, metabolic syndrome, cystinorrhea, and patients who have undergone drug therapy other than L-carnitine for kidney or ureteral stone

Intervention groups

Patients with a history of recurrent stone formation that treated with vial L-carnitine for one gram daily for eight weeks

Main outcome variables

24-hour urine calcium, 24-hour urine uric acid, 24-hour urine oxalate and 24-hour urine citrate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191209045675N1**

Registration date: **2020-01-15, 1398/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-15, 1398/10/25**

Update count: **0**

Registration date

2020-01-15, 1398/10/25

Registrant information

Name

Naser Tabibian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3033

Email address

tabibian.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-10, 1398/10/20

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of L-carnitine on the metabolites of 24-hour urine in patients with a history of recurrent stone formation.

Public title

Effect of L-carnitin on the stone formation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with a history of renal stone passage Patients undergoing surgical or non-surgical (ESWL) surgery for kidney or ureteral stones

Exclusion criteria:

Patients with anatomical disorders Patients who first have kidney stones Patients with endocrine disorders including hyperparathyroidism, diabetes mellitus, metabolic syndrome, cystinuria .. Patients who have been on medications other than L-carnitine for kidney or ureteral stones

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

University City, Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2019-11-27, 1398/09/06

Ethics committee reference number

IR.AJUMS.REC.1398.633

Health conditions studied**1****Description of health condition studied**

Renal Stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes**1****Description**

24 hour urine calcium

Timepoint

Before intervention and 8 weeks after starting L-carnitine vial

Method of measurement

Colorimetric

2**Description**

24 hour urine oxalate

Timepoint

Before intervention and 8 weeks after starting L-carnitine vial

Method of measurement

Colorimetric

3**Description**

24 hour urine uric acid

Timepoint

Before intervention and 8 weeks after starting L-carnitine vial

Method of measurement

Colorimetric

4**Description**

24 hour urine citrate

Timepoint

Before intervention and 8 weeks after starting L-carnitine vial

Method of measurement

Colorimetric

Secondary outcomes

empty

Intervention groups

1

Description

This study has no control group. The intervention group consisted of subjects with renal stone that had a history of recurrent stone formation for 8 weeks receiving one gram of oral vial L-carnitine daily (a number of one gram of oral vial) of Zist Takhmir pharmaceutical company product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology Clinic of Golestan Hospital of Ahvaz

Full name of responsible person

Dr. Alireza Kheradmand

Street address

Urology Clinic, Golestan Hospital, Farvardin Ave,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Naser Tabibian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Position

Assistant Professor

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Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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

The patient's 24-hour urine results can be published

When the data will become available and for how long

Access time is up to 6 months after the results are published

To whom data/document is available

Information will only be available to researchers working in universities and science centers

Under which criteria data/document could be used

The control of the data and supplementary analyses of the data could be performed under copyright law

From where data/document is obtainable

Applicants can be contacted by email with the author to receive the requested data

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

Applicants will receive the data from the current study by sending an email to the author responsible for a maximum of one month

Comments