Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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(extracorporal 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, cystinorrhoea, 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)

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+98 61 3374 3033

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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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Urology

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Person responsible for updating data

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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