Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effects of oral sodium thiosulfate in patients with calcium kidney stones: A randomized, double-blind clinical trial

Protocol summary

Study aim

Evaluation of oral sodium thiosulfate effects in patients with calcium kidney stones

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3, with a sample size of 70 patients. For randomization, the clinical trial randomization tool was used.

Settings and conduct

This double-blind randomized controlled clinical trial will be carried out on 70 patients aged 18 to 80 with calcium kidney stones who are candidates for treatment and who refer to the clinic or inpatient department of Imam Reza Hospital. Demographic information, other drugs received and clinical status of patients will be recorded in the initial checklist of the study. In addition to the standard treatment, the intervention group will receive oral sodium thiosulfate at a dose of 3 grams daily for 3 months. In the control group, patients will receive placebo along with the standard treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- People over 18 years old with kidney stones who are candidates for standard treatment. 2- Recurrent kidney stone disease 3- Any previous kidney stones containing 50% or more calcium oxalate, calcium phosphate, or a mixture of both.

Intervention groups

Patients in the intervention group will receive 3 grams of oral sodium thiosulfate daily in addition to the usual treatments for 3 months. Patients in the control group will also receive placebo for 3 months.

Main outcome variables

Patients will be examined in terms of changes in the dimensions of kidney stones (by ultrasound) as a primary outcome, as well as urine tests and serum levels of various parameters, clinical symptoms related to stones and possible side effects caused by medicine and placebo.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231017059748N2**
Registration date: **2023-10-22, 1402/07/30**
Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**
Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name

Hadi Hamishehkar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3337 2250

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of oral sodium thiosulfate in patients with calcium kidney stones: A randomized, double-blind clinical trial

Public title
Effects of oral sodium thiosulfate in patients with calcium kidney stones

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over 18 years old with kidney stones who are candidates for standard treatment. Recurrent kidney stone disease Any previous kidney stones containing 50% or more calcium oxalate, calcium phosphate, or a mixture of both.

Exclusion criteria:
Active malignancy Patients using SGLT2i drugs, topiramate, carbonic anhydrase inhibitors, loop diuretics, glucocorticoids, laxatives Electrolyte disorders: hypokalemia (blood potassium level less than 3 mmol/L) or hypernatremia (blood sodium level >145 mmol/L) in initial tests Urinary tract infection if not treated successfully Pregnant and lactating women Participation in another clinical trials Inability to understand and follow protocol Known allergy to the study medicine

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be carried out using the random allocation site (https://www.sealedenvelope.com/simple-randomiser/v1/lists) by blocked randomization method with random block size 4 and 6.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind and none of the patients and researchers will know about the process of assigning patients to the intervention and placebo groups. For this purpose, sodium thiosulfate and placebo will be similarly packaged and given to the patient. Also, sodium thiosulfate and placebo tablets will have the same shape, color, and size.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2023-08-07, 1402/05/16

Ethics committee reference number
IR.TBZMED.REC.1402.379

Health conditions studied

1

Description of health condition studied
Nephrolithiasis (calcium stones)

ICD-10 code
N20

ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
Reducing the size of calcium kidney stones

Timepoint
Baseline, After 1 month, And after 3 months

Method of measurement
Sonography

Secondary outcomes

1

Description
The rate of improvement in complications and clinical symptoms of kidney stones

Timepoint
Baseline, After 1 month, And after 3 month

Method of measurement
Questionnaire

2

Description
Changes in serum levels of electrolytes, BUN, creatinine, liver enzymes, CBC and urinalysis
Timepoint
Baseline, After 1 month, And after 3 month
Method of measurement
Blood and urine samples

3

Description
The incidence and severity of possible side effects caused by sodium thiosulfate
Timepoint
Baseline, After 1 month, And after 3 month
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Patients will receive 3 grams of oral sodium thiosulfate daily in addition to the usual treatments for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Patients will receive a placebo daily for 3 month along with usual treatments.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nephrology Clinic, Imam Reza Hospital, Tabriz
Full name of responsible person
Hadi Hamishehkar
Street address
Imam Reza Educational and Medical Center, in front of the central organization of the University, Golgasht St., Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street
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5165665931
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+98 41 3335 7310
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Hadi Hamishehkar
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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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
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All of the data of an article can be published after making patients unrecognized.

When the data will become available and for how long
After publishing of article until 6 months after publishing of the results

To whom data/document is available
Data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Researchers who request data will be permitted only to do analysis according to ethics for scientific aims.

From where data/document is obtainable
Applicants can receive data by sending an E-mail to address of hamishehkar@gmail.com and get response from Dr. Hadi Hamishehkar.

What processes are involved for a request to access data/document
After contacting the corresponding author(Dr. Hadi Hamishehkar), data will be sent to the Tabriz Imam Reza hospital ethics committee and after receiving permission, data will be sent to applicants.

Comments