

# 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)

##### Phone

+98 41 3337 2250

##### Email address

hamishehkar@gmail.com

##### 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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614756

##### **Phone**

+98 41 3334 7054

##### **Email**

hamishehkar@gmail.com

## **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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5165665931

##### **Phone**

+98 41 3335 7310

##### **Email**

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

##### **Street address**

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## Person responsible for scientific inquiries

### Contact

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Tabriz University of Medical Sciences

**Full name of responsible person**

Hadi Hamishehkar

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Professor

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Specialist

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## Person responsible for updating data

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Hadi Hamishehkar

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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