

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of Nigella sativa and honey combination effect on kidney stone: A clinical Trial

#### Protocol summary

##### Study aim

Evaluation of Nigella sativa and honey combination effect on kidney stone expulsion in human

##### Design

randomized clinical trial with control group - parallel groups,

##### Settings and conduct

A clinical trial will be conducted on 40 eligible patients who will refer to the urology clinic of Dezful Ganjavian Hospital and will be identified by a sonographer that they have kidney stones smaller than 6 mm. They will be randomly assigned to control and treatment groups. The treatment group will take 8 grams of the product with one glass of warm water daily for one month. The control group will not receive medication. Both groups will drink 6-8 glasses of water per day. At the end, sonography will repeat. Blood and urine biochemical test, 24h urine volume and urine pH will determine before and after intervention too. At last the rate of stone expulsion will compare in two groups with SPSS 22 software.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age > 18, stone size > 6 mm, Asymptomatic and without hydronephrosis, No need to medication; Exclusion criteria: Pregnancy, History of the complication or sensitivity to black seed, Receiving drugs that affect kidney stones, Use of stone crushing techniques, Diabetes

##### Intervention groups

Control group: Receive 8 glasses of water for one month each day. Intervention group: Receive 8 glasses of water + 8 grams of product (po) for one month each day

##### Main outcome variables

Excreted kidney stone number

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111105008013N6**

Registration date: **2018-11-15, 1397/08/24**

Registration timing: **retrospective**

Last update: **2018-11-15, 1397/08/24**

Update count: **0**

##### Registration date

2018-11-15, 1397/08/24

##### Registrant information

###### Name

Amir Siahpoosh

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3334 2197

###### Email address

siahpoosh-a@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-10-07, 1397/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Nigella sativa and honey combination effect on kidney stone: A clinical Trial

##### Public title

Nigella sativa and honey effect on kidney stone

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

age>18 stone size> 8 mm Asymptomatic and without hydronephrosis No need to medication

### Exclusion criteria:

pregnancy History of the complication or sensitivity to black seed Receive drugs that affect kidney stones Use of stone crushing techniques Diabetes

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization The site of <https://www.randomizer.org> will be used for simple randomization.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## 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

Golestan Road

##### City

ahvaz

##### Province

Khuzestan

##### Postal code

6135733184

#### Approval date

2017-12-02, 1396/09/11

#### Ethics committee reference number

IR.AJUMS.REC.1396.645

## Health conditions studied

### 1

#### Description of health condition studied

kidney stone

#### ICD-10 code

N20.0

#### ICD-10 code description

Calculus of kidney

## Primary outcomes

### 1

#### Description

Excreted kidney stone number

#### Timepoint

Start of intervention and a month later

#### Method of measurement

Ultrasonography and blood and urine tests

## Secondary outcomes

### 1

#### Description

urine volume 24 h

#### Timepoint

Start of intervention and a month later

#### Method of measurement

Urine 24 h test by BT-1500 autoanalyser

### 2

#### Description

Creatinine in urine 24h

#### Timepoint

Start of intervention and a month later

#### Method of measurement

Urine 24h test by Pars Azmoon kit

### 3

#### Description

oxalate in urine 24 h

#### Timepoint

Start of intervention and a month later

#### Method of measurement

urine 24 h test by Darmankau kit

### 4

#### Description

Citrate in urine 24 h

#### Timepoint

Start of intervention and a month later

#### Method of measurement

urine 24 h test by Darmankau kit

## 5

### **Description**

Uric acid in urine 24 h

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

urine 24h test by Pars Azmoon kit

## 6

### **Description**

Calcium in urine 24 h

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

urine 24h test by Pars Azmoon kit

## 7

### **Description**

Urine specific gravity

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Urinalysis by BT-1500 autoanalyser

## 8

### **Description**

urine pH

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Urinalysis by BT-1500 autoanalyser

## 9

### **Description**

Urine protein

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Urinalysis by BT-1500 autoanalyser

## 10

### **Description**

Urine Cystine

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Urinalysis with Spectrophotometer

## 11

### **Description**

Serum creatinine

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Blood test by Pars Azmoon kit

## 12

### **Description**

Serum calcium

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Blood test by Pars Azmoon kit

## 13

### **Description**

Serum phosphorus

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Blood test by BT-1500 autoanalyser

## 14

### **Description**

Serum uric acid

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Blood test by Pars Azmoon kit

## 15

### **Description**

BUN

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Blood test by BT-1500 autoanalyser

## 16

### **Description**

Stone size

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Sonography

## **Intervention groups**

### 1

#### **Description**

Control group: Receive 8 glasses of water for one month each day.

#### **Category**

Placebo

### 2

#### **Description**

Intervention group: Receive 8 glasses of water + 8 grams of product (po) for one month each day

#### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Ganjavian Hospital  
**Full name of responsible person**  
Mr. Dr. Eskand Moghimipour  
**Street address**  
Dezful  
**City**  
Dezful  
**Province**  
Khuzestan  
**Postal code**  
6461863915  
**Phone**  
+98 61 4252 2952  
**Email**  
DARMAN@DUMS.AC.IR  
**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr Mohamad badavi  
**Street address**  
Ahvaz- golestan road  
**City**  
Ahvaz  
**Province**  
Khuzestan  
**Postal code**  
6135733184  
**Phone**  
+98 61 3336 2414  
**Email**  
amirsiahpoosh@yahoo.com  
**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**  
Laleh Zaheri Abdehvand  
**Position**  
Ph.D. student of traditional pharmacy  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Ph.D traditional pharmacy  
**Street address**  
Ahvaz, golestan road  
**City**  
Ahvaz  
**Province**  
Khuzestan  
**Postal code**  
6135733184  
**Phone**  
+98 61 3337 5356  
**Email**  
lalehzaheri44@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Amir Siahpoosh  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
فارماکونوزی  
**Street address**  
Golestan Road - Ahvaz  
**City**  
Ahvaz  
**Province**  
Khuzestan  
**Postal code**  
6135733184  
**Phone**  
+98 61 3334 2197  
**Email**  
lalehzaheri44@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Laleh Zaheri Abdehvand  
**Position**  
Ph.D. student of traditional pharmacy

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Ph.D. traditional pharmacy

**Street address**

Golestan Road -

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135733184

**Phone**

+98 61 3334 2197

**Email**

lalehzaheri44@gmail.com

**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**

Only part of the data will be shared.

**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**

Six months after the publication of the papers from this study, the data obtained will be available to the applicant researchers for further analysis.

**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**