# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 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 sonographist 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**
Conrol 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)

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+98 61 3334 2197

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**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**

Khouzestan

**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**
Conrol 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
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**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
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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**
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## Person responsible for scientific inquiries

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Amir Siahpoosh
**Position**
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## Person responsible for updating data

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**Other areas of specialty/work**
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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**
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**