Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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)

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

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
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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
Laleh Zaheri Abdehvand
Position
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Person responsible for scientific inquiries

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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
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