

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of single-step alcohol injection and maintenance of drainage catheter on treatment of simple renal cysts: a before-after clinical trial

Protocol summary

Summary

Objectives: To assess the effect of single-step alcohol injection and maintenance of drainage catheter on treatment of simple renal cysts. **Design:** A before-after clinical trial. **Setting and conduct:** The eligible patients with simple renal cysts who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** Age of 30 to 65 years; simple renal cyst with a size of larger than 4 cm with signs and symptoms such as flank pain or abdominal pain or hematuria or high blood pressure or pressure effect on ureter or pelvic. **Exclusion criteria:** Autosomal dominant renal polyp cystitis; infectious kidney cysts; cystic tumors; previous treated cysts; coagulopathy. **Intervention group:** Single dose injection of ethanol 95% intra cyst up to 100 ml and maintenance of drainage catheter for 5 days. **Control group:** In comparison with before intervention. **Primary outcome:** Assessing renal cyst 3 and 6 months after treatment using sonography. **Randomization:** This is a before after trial without randomization **Blinding:** Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710309014N198**

Registration date: **2017-10-31, 1396/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-31, 1396/08/09

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-06-09, 1395/03/20

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of single-step alcohol injection and maintenance of
drainage catheter on treatment of simple renal cysts: a
before-after clinical trial

Public title

Effect of single-step alcohol injection and maintenance of
drainage catheter on treatment of simple renal cysts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 30 to 65 years; simple renal cyst
with a size of larger than 4 cm with signs and symptoms
such as flank pain or abdominal pain or hematuria or
high blood pressure or pressure effect on ureter or

pelvic. Exclusion criteria: Autosomal dominant renal polyp cystitis; infectious kidney cysts; cystic tumors; previous treated cysts; coagulopathy.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Randomization: This is a before after trial without randomization
Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Approval date

2016-06-07, 1395/03/18

Ethics committee reference number

IR.UMSHA.REC.1395.9

Health conditions studied

1

Description of health condition studied

Simple renal cysts

ICD-10 code

N28.1

ICD-10 code description

Cyst of kidney, acquired

Primary outcomes

1

Description

Assessing renal cyst

Timepoint

3 and 6 months after treatment

Method of measurement

Using sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Single dose injection of ethanol 95% intra cyst up to 100 ml and maintenance of drainage catheter for 5 days.

Category

Treatment - Drugs

2

Description

Control group: In comparison with before intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Mohsen Alemi

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice-chancellor for Research and Technology, Hamadan
 University of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact
Name of organization / entity
 Shahid Beheshti Hospital
Full name of responsible person
 Dr Mohsen Alemi
Position
 Urologist
Other areas of specialty/work
Street address
 Shahid Beheshti Hospital, Eram Ave.
City
 Hamadan
Postal code
Phone
 +98 81 3838 0283
Fax
Email
 mohsenalemi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Shahid Beheshti Hospital
Full name of responsible person
 Dr Mohsen Alemi
Position
 Urologist

Other areas of specialty/work
Street address
 Shahid Beheshti Hospital, Eram Ave.
City
 Hamadan
Postal code
Phone
 +98 81 3838 0283
Fax
Email
 mohsenalemi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
 Department of Epidemiology
Full name of responsible person
 Dr Jalal Poorolajal
Position
 Professor of Epidemiology
Other areas of specialty/work
Street address
 School of Public Health, Hamadan University of
 Medical Sciences, Shahid Fahmideh Ave
City
 Hamadan
Postal code
Phone
 +98 81 3838 0090
Fax
Email
 poorolajal@umsha.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty