Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the results and complications Laparoscopic removal of renal cysts with percutaneous drainage and sclerosing injections

Protocol summary

Study aim
Comparison of the results and complications Laparoscopic removal of renal cysts with percutaneous drainage and sclerosing injections

Design
The study is a randomized, community-based, and pragmatic clinical trial consisting of 80 patients in 2 parallel groups with double-blind design

Settings and conduct
This study will be carried out at Tabriz Imam Hospital in a two-blind manner

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients with a simple kidney cyst in the upper part,Patients with a simple kidney cyst with a size of more than 4 cm . Exclusion criteria: patients with polycystic, kidney Patients with infectious renal cysts, patients with cystic tumors, Patients with coagulopathy

Intervention groups
Intervention group: Injection of sclerosant into the cyst, Control group: Renal cyst removal by laparoscopic surgery

Main outcome variables
Duration of intervention,The recurrence rate of Kidney cyst,The rate of complications after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231127060199N1**
Registration date: **2024-01-15, 1402/10/25**
Registration timing: **prospective**

Last update: **2024-01-15, 1402/10/25**
Update count: **0**

Registration date
2024-01-15, 1402/10/25

Registrant information

Name
Masoud ghofrani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 7054

Email address
drmasoudghofrani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-08-20, 1403/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the results and complications Laparoscopic removal of renal cysts with percutaneous drainage and sclerosing injections

Public title
Comparison of the complications of renal cysts with laparoscopic removal and percutaneous cyst drainage

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with a simple kidney cyst in the upper part of the kidney Patients with a simple kidney cyst with a size of more than 4 cm

Exclusion criteria:

patients with polycystic kidney Patients with infectious renal cysts patients with cystic tumors Patients with coagulopathy

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

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups by last digit of the patient's file number . Even number for group laparoscopic removal of renal cysts and odd number for percutaneous drainage and sclerosing injections

Blinding (investigator's opinion)
Double blinded

Blinding description
After selecting study groups based on last digit of the patient's file number. 1 and 2 labels were assigned to the target group by the secretary. Then, the patients will be intervened by the researcher in the operating room in the case group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz Medical School

Street address
No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Approval date
2023-06-12, 1402/03/22

Ethics committee reference number
IR.TBZMED.REC.1402.220

Health conditions studied

1

Description of health condition studied
Simple kidney cysts

ICD-10 code
N28.1

ICD-10 code description
Cyst of kidney, acquired

Primary outcomes

1

Description
Duration of intervention

Timepoint
From the start of surgery to the end of surgery

Method of measurement
period of time

2

Description
Duration of admitted

Timepoint
From admission to discharge

Method of measurement
Hospitalization day

Secondary outcomes

1

Description
The rate of complications after the intervention

Timepoint
At 3th,6th months after surgery

Method of measurement
Physical examination

2

Description
he recurrence rate of Kidney cyst

Timepoint
At 3th,6th months after surgery

Method of measurement
Physical examination

Intervention groups

1

Description
Intervention group: Intralesional Bleomycin Sclerotherapy: In patients in this group, injections are performed by one person and under ultrasound guide in the operating room and under general anesthesia. After a general examination of the cyst with examination and ultrasound in the operating room, first the fluid contents

of the cysts are repeatedly emptied under the ultrasound guide by a 10 cc syringe and needle number 21. While the needle head is in the same place inside the cyst and the control is done by sono, the sclerosing substance is injected at the site. The required dose is 0.5 units per kilogram of body weight. The maximum amount of injection to prevent possible complications is 10 units of sclerosing material.

Category
Treatment - Surgery

2

Description
Intervention group: Renal cyst removal by laparoscopic surgery

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Urology Ward, Imam Reza Hospital,

Full name of responsible person
Alireza Farshi

Street address
Golgasht ave,imam reza Hhospital

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 916 276 3495

Email
dr.ramezanireza70@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Samiee

Street address
Golgasht Street. Research and Technology, University of Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Phone
+98 914 117 0855

Email
hajebrahimis@gmail.com

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
Mohsen Mohammad Rahimi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Urology

Street address
Urology Ward,Imam Reza Hospital, Golgasht St.,Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 41 3334 7054

Email
mm.rahimi1357@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Alireza Farshi

Position
professor

Latest degree
Specialist

Other areas of specialty/work
Urology

Street address

Urology Ward,Imam Reza Hospital, Golgasht St.,Tabriz,

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 41 3337 6923

Email
dr.ramezanireza70@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Masoud Ghofrani behnag

Position
Urology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

Street address
Urology Ward,Imam Reza Hospital, Golgasht St.,Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 41 3334 7054

Email
drmasoudghofrani@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
A portion of the data that represents the final outcome

When the data will become available and for how long
Access will be 6 months after the results are printed

To whom data/document is available
Urological specialists in coordination with the presenter

Under which criteria data/document could be used
The use of data to improve patients' treatment processes is safe

From where data/document is obtainable
The person responsible for updating study information

What processes are involved for a request to access data/document
Requesting data and study documents will be done by correspondence with the person responsible for updating the study information

Comments