

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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+98 41 3334 7054

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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

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Golgasht ave,imam reza Hhospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiee

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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

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

Medical doctor

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

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