

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of success rate and complications of mini PCNL with ESWL in treatment of <2cm lower pole kidney stones

Protocol summary

2019-04-05, 1398/01/16

Study aim

Comparison of success rate and complications of mini PCNL with ESWL in treatment of lesser than 2cm lower pole kidney stones.

Design

Example 4: A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 501 patients, enrolled between October 2008 and September 2012, and followed for one year

Settings and conduct

khuzetan, Emam hospital, clinical trial

Participants/Inclusion and exclusion criteria

inclusion criteria: Kidney stones are less than 2 cm in the lower calyx renal. age of patients is between 18 to 65 years old
Exclusion criteria: Patients with a history of coagulation disorders. The patient has an active urinary tract infection. Women who are pregnant

Intervention groups

group A: Patients will be treated with direct access to mini PNL method utilized inferior Cullis
group B: Patients will be treated with standard ESWL method.

Main outcome variables

BMI, Hb drop, hospital stay, stone free rate, stone opacity, kind of therapeutic procedure, satisfaction of patient, SFR time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190219042765N1**

Registration date: **2019-04-05, 1398/01/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-05, 1398/01/16**

Update count: **0**

Registration date

Registrant information

Name

Mahbubeh Saleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3337 3033

Email address

mbbslh1397@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-29, 1398/01/09

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of success rate and complications of mini PCNL with ESWL in treatment of <2cm lower pole kidney stones

Public title

Effect of mini Nephrolithotomy and Lithotripter in treatment of kidney stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Kidney stones are less than 2 cm in the lower calyx renal. age of patients is between 18 to 65 years old.

Exclusion criteria:
Patients with a history of coagulation disorders. The patient has an active urinary tract infection. Women who are pregnant.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the 4-block method, individuals will be divided randomly into two equal groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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 Blvd

City

ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2019-02-15, 1397/11/26

Ethics committee reference number

IR.AJUMS.REC.1397.850

Health conditions studied

1

Description of health condition studied

renal stone

ICD-10 code

N20.0

ICD-10 code description

Calculus

Primary outcomes

1

Description

Time of Hospitalization

Timepoint

The duration of treatment

Method of measurement

The duration of hospitalization

2

Description

Time of free of stone

Timepoint

24 and 48 hours after surgery

Method of measurement

With clinical examination

Secondary outcomes

1

Description

Hemoglobin decline

Timepoint

24 and 48 hours after surgery

Method of measurement

With laboratory examination

Intervention groups

1

Description

Intervention group: Patients will be treated with direct access to mini PNL method utilized inferior Cullis group

Category

Treatment - Surgery

2

Description

Intervention group: Patients will be treated with standard ESWL method.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hospital

Full name of responsible person

Mahbobeh Saleh

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Shahid ahvazian stress

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Postal code

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Email

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Position

Resident of Urology

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohamadreza Dadfar

Street address

Golestan street, Shahr Daneshgahi, Deputy of
Research and Technology Development of Ahvaz
Jondishapur University of Medical Sciences, Ahvaz.

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itc@ajums.ac.ir

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

mahboobeh Saleh

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohamadreza Dadfar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Dr. Mahboobeh Saleh

Position

Resident of Urology

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available