Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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 betwwn 18 to 65 years old Exclusuion 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 theraputic 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
2019-04-05, 1398/01/16

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 withESWL in treatment of <2cm lower pole kidney stones

Public title
Effect of mini Nephrolithotomy and Lithotriptor 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 betwwn 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

Street address
Shahid ahvazian stress
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3222 2818
Email
mbbslh1397@yahoo.com

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.
City
ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3336 2414
Email
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
Position
Resident of Urology
Latest degree
Medical doctor
Other areas of specialty/work
Urology
Street address
Shahid ahvazian streert
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3222 2818
Email
mbbslh1397@yahoo.com

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
Street address
Khuzestan Province, Ahvaz, shaid ahvazian street, Emam Hospital
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3222 2818
Email
mdadfar@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mahboobeh Saleh
Position
Resident of Urology
Latest degree
Medical doctor
Other areas of specialty/work
Urology
Street address
Khuzestan Province, Ahvaz, Shahid ahvazian street,

Emam Hospital
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3222 2818
Email
mbbslh1397@yahoo.com

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