

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the Surgical Outcome of Laparoscopic-assisted Extracorporeal Pyeloplasty and Open Dismembered Pyeloplasty in Children with Ureteropelvic Junction Obstruction

Protocol summary

Summary

Objective: Comparison of the Surgical Outcome of Laparoscopic-assisted Extracorporeal Pyeloplasty and Open Dismembered Pyeloplasty in Children with Ureteropelvic Junction Obstruction. Design: Interventional, Not-blinded, Non-randomized. Target sample size: 50 People. Inclusion Criteria: Children under age 14. Exclusion Criteria: Dyspepsia; Gastroesophageal reflux disease (GERD) along with ipsilateral UPJO; Any history of ipsilateral UPJO surgery; Anatomical abnormalities such as ectopic or duplicated ureter; Other urinary tract anomalies; Presented contraindications to surgery; Any history of previous abdominal surgery; Abdominal diseases and interventions; Underlying diseases such as coagulopathy. Intervention group: Surgery of Laparoscopic-assisted Extracorporeal Pyeloplasty. Control group: Surgery of open Dismembered Pyeloplasty. Primary outcome measure: During hospitalization period, After surgery, Via hospitalized form; Surgery results, Till 6 months after surgery, Using Clinical examinations.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010920621N1**
Registration date: **2015-02-25, 1393/12/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-25, 1393/12/06

Registrant information

Name

Parisa Saeedi

Name of organization / entity

Sheykh Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 4499

Email address

saeedipp@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Surgical Outcome of Laparoscopic-assisted Extracorporeal Pyeloplasty and Open Dismembered Pyeloplasty in Children with Ureteropelvic Junction Obstruction

Public title

Treatment of Ureteropelvic Junction Obstruction in infants and children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Children under age 14. Exclusion

Criteria: Dyspepsia; Gastroesophageal reflux disease (GERD) along with ipsilateral UPJO; Any history of ipsilateral UPJO surgery; Anatomical abnormalities such as ectopic or duplicated ureter; Other urinary tract anomalies; Presented contraindications to surgery; Any history of previous abdominal surgery; Abdominal diseases and interventions; Underlying diseases such as coagulopathy

Age
To **14 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

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

Vice Chancellor for Research, Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi Building, Daneshgah St, Mashhad

City

Mashhad

Postal code

Approval date

2011-07-28, 1390/05/06

Ethics committee reference number

900568

Health conditions studied

1

Description of health condition studied

Uretropelvic junction obstruction in infants

ICD-10 code

Q62.1

ICD-10 code description

Atresia and stenosis of ureter

Primary outcomes

1

Description

During hospitalization period

Timepoint

After surgery

Method of measurement

Hospitalized form

2

Description

Surgery results

Timepoint

Till 6 months after surgery

Method of measurement

Clinical examinations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Surgery of Laparoscopic-assisted Extracorporeal Pyeloplasty

Category

Treatment - Surgery

2

Description

Control group: Surgery of open Dismembered Pyeloplasty

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykh Hospital

Full name of responsible person

Parisa Saeedi

Street address

Sheykh Hospital, Gharani 6th St, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Ramezani

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi Building, Daneshgah St, Mashhad

City

Mashhad

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, Mashhad 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**

Sheikh Hospital

Full name of responsible person

Parisa Saeedi

Position

Resident

Other areas of specialty/work**Street address**

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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