

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Results of early pyeloplasty and maintenance therapy in asymptomatic infants with grade III and IV ureteropelvic junction obstruction(UPJO)

Protocol summary

Study aim

Results of early pyeloplasty and maintenance therapy in asymptomatic infants with grade III and IV ureteropelvic junction obstruction (UPJO)

Design

Patients will be randomly divided into two groups and therapeutic results of each group will be evaluated.

Settings and conduct

The location of the study is in the Mofid children's hospital of Tehran. All surgeries are performed by a single surgery team and a type of surgery is approved by the surgeons of this centre.

Participants/Inclusion and exclusion criteria

All asymptomatic children under the age of one year with ureteropelvic junction obstruction (UPJO) (grade 3 or 4 hydronephroses) proven with ultrasound and their differential renal function (DRF) based on the results of isotope scans should be least 40% or higher

Intervention groups

Asymptomatic children under the age of one who has UPJO Grade 3 and Grade 4. After obtaining a consent form, will randomly be divided into two groups, the first group will be treated non-surgically, and the second group will be assigned early Pyeloplasty Then, during a one-year period, patients will be monitored by urine analysis ultrasound and isotope scans.

Main outcome variables

The degree of ureteropelvic junction obstruction

General information

Reason for update

Acronym

UPJO

IRCT registration information

IRCT registration number: **IRCT20180310039030N1**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **retrospective**

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Khashayar Atqiaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3891 8707

Email address

khashayar_atqiaee@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Results of early pyeloplasty and maintenance therapy in asymptomatic infants with grade III and IV ureteropelvic junction obstruction(UPJO)

Public title

Comparison of Surgical and non-surgical therapies in Infants with ureteropelvic junction obstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All asymptomatic children under one year of age with ureteropelvic junction obstruction (UPJO) (grade 3 or 4 hydronephroses) The kidney differential function (DRF) is based on the results of isotope scans at least 40% or higher.

Exclusion criteria:

All children under one year of age with ureteropelvic junction obstruction(UPJO) with symptoms such as urinary tract infections, palpable kidney pain The presence of ureteral and kidney anomalies Ultrasonography represents structural anomalies voiding cystourethrogram (VCUG) represents urinary reflux and posterior urethral valve (PUV)

Age

From **1 month** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Patients are randomly assigned to one of the two intervention and follow-up groups based on the last digit of the case file. Persons with even numbers categorise as the intervention group and the persons with odd numbers categorise in the follow-up group.

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 Shahid Beheshti University of Medical Sciences

Street address

Mofid children Hospital, Shariati Ave

City

Tehran

Province

Tehran

Postal code

15468- 155514

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.SBMU.MSP.REC.1397.590

Health conditions studied**1****Description of health condition studied**

Ureteropelvic Junction Obstruction

ICD-10 code

N13.1

ICD-10 code description

Hydronephrosis with ureteropelvic junction obstruction

Primary outcomes**1****Description**

The degree of Ureteropelvic Junction Obstruction

Timepoint

before intervention 1 week later 3 and 6 months later to one year

Method of measurement

Ultra sonography ,radioisotope scan

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: asymptomatic patient under age of one year with ureteropelvic junction obstruction undergoing dismembered reduction pyeloplasty

Category

Treatment - Surgery

2**Description**

Control group: asymptomatic patient under age of one year with ureteropelvic junction obstruction undergoing maintenance therapy. Follow up visits to the treatment center at specific intervals. At monthly urine test, ultrasound and isotope scans at intervals of 3 months 6 months to 1 year to check the progression of the disease.

Category

Treatment - Other

Recruitment centers**1****Recruitment center**

Name of recruitment center

Mofid Children Hospital
Full name of responsible person
Khashayar Atqiaee
Street address
Mofid Children Hospital shariati Ave
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Velenjak St. , Shahid Chamran Highway
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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Khashayar Atqiaee
Position
pediatric surgery resident
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After the end of the study, the individual data of the participants in the study, which includes all the potential data after the unidentifiable individuals are shared

When the data will become available and for how long

The release date of this document/data file is 6 months after the publication of the results

To whom data/document is available

Our data will only be available to researchers working scientific and academic institutions

Under which criteria data/document could be used

Data usage is allowed if no change is made in the data and if the analysis of data needed, inform the author

From where data/document is obtainable

You can access the requested items by email to the author

What processes are involved for a request to access data/document

Information will be sent to you within 5 business days after the email is sent to the author

Comments

Contact the author by email if you need additional information