

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison between surgical and conservative treatment for severe Ureteropelvic junction obstruction in pediatrics

Protocol summary

Study aim

Comparison of expectant and surgical therapy for children suffering from ureteropelvic junction obstruction (UPJO)

Design

A non randomized, double blind, sham controlled clinical trial with a parallel group design, consisted of 30 patients, enrolled between February 2020 and February 2021, and followed for one year.

Settings and conduct

The study will be performed on less than 18 year-old children referred to Boali hospital from February 2020 to February 2021. Sonography to diagnose severity of hydronephrosis, VCUG to diagnose vesico-ureteral reflux (VUR) and renal scan to assess severity of obstruction will be ordered. Radiologists, Scintigraphy reporters and main co-workers are blinded to patients' grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Less than 18 years of age, history of prenatal or postnatal severe hydronephrosis on sonography, Normal VCUG, Obstructive renal scan with diminished renal function. Exclusion criteria: Vesicoureteral Reflux, Bilateral hydronephrosis, Neurogenic bladder, Multicystic dysplastic kidney, unwillingness to participation

Intervention groups

Intervention group: Those patients with severe hydronephrosis who underwent surgical operation for obstruction (pyeloplasty). Control group: Those patients with severe hydronephrosis who didn't undergo surgical operation for obstruction (pyeloplasty).

Main outcome variables

Anteroposterior renal pelvic diameter; Grade of hydronephrosis; Improvement of obstruction and function of kidney on renal scan.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141224020419N4**

Registration date: **2020-06-10, 1399/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-10, 1399/03/21**

Update count: **0**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Hamid Mohammadjafari

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between surgical and conservative treatment for severe Ureteropelvic junction obstruction

in pediatrics	of Medical Sciences, Moalem square
Public title	City
UPJO treatment	Sari
Purpose	Province
Treatment	Mazandaran
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	4818856361
All less than 18 yr old patients with grade 3 or 4 hydronephrosis on prenatal all after birth sonography.	Approval date
Normal VCUG Severe obstruction and diminished function on functional renal scan.	2019-12-02, 1398/09/11
Exclusion criteria:	Ethics committee reference number
Vesicoureteral Reflux Bilateral Hydronephrosis	IR.MAZUMS.REC.1398.1174
Neurogenic Bladder Multicystic kidney Not willing to contribute in the study	
Age	Health conditions studied
To 18 years old	1
Gender	Description of health condition studied
Both	Urinary Tract Obstruction
Phase	ICD-10 code
N/A	N13.1
Groups that have been masked	ICD-10 code description
- Investigator - Outcome assessor - Data analyser - Data and Safety Monitoring Board	Hydronephrosis with ureteral stricture, not elsewhere classified
Sample size	2
Target sample size: 30	Description of health condition studied
Randomization (investigator's opinion)	congenital Hydronephrosis
Not randomized	ICD-10 code
Randomization description	Q62.0
Blinding (investigator's opinion)	ICD-10 code description
Double blinded	Congenital hydronephrosis
Blinding description	Primary outcomes
Improvement status is the main variable that should be blinded. Therefore radiologist and scintigraphic reporters will be blinded. The scintigraphy reporter will be blinded in all times. But the sonographer will be blinded before operation. It is impossible to blind sonographer after surgery because of scar.	1
Placebo	Description
Not used	Severity of Hydronephrosis in sonography
Assignment	Timepoint
Parallel	Before intervention and 3 months and 6 months later
Other design features	Method of measurement
	Sonography
Secondary Ids	2
empty	Description
	Obstruction severity
	Timepoint
	Before intervention and 12 months later
	Method of measurement
	Dynamic Renal Scan
Ethics committees	Secondary outcomes
1	empty
Ethics committee	Intervention groups
Name of ethics committee	1
Ethics committee of Māzandarān University of Medical Sciences	Description
Street address	
Vice Chancellor for research, Mazandaran University	

Intervention group: Hydronephrotic children (less than 18 years) with severe obstruction that are treated with surgical intervention (pyeloplasty).

Category

Treatment - Surgery

2

Description

Control group: Hydronephrotic children (less than 18 years) with severe obstruction that are not treated with surgical intervention (pyeloplasty).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali hospital

Full name of responsible person

Mahgol Sadeghian

Street address

Pasdaran boulevard

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mahgol Sadeghian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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