

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

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hmjafari@mazums.ac.ir

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

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**

Sari

**Province**

Mazandaran

**Postal code**

4818856361

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Street address**

Vice Chancellor for research, Mazandaran University of Medical Sciences, Moalem square

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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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Hamid Mohamadjafari

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mahgol Sadeghian

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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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