ISRCTN15328718 https://doi.org/10.1186/ISRCTN15328718

# Analysis of operating time and safety of laparoscopic pyeloplasty with or without TriSect rapide® in adult patients with ureteropelvic junction obstruction

**Submission date**
07/08/2025

**Recruitment status**
No longer recruiting

**Registration date**
11/08/2025

**Overall study status**
Completed

**Last Edited**
17/07/2026

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Laparoscopic pyeloplasty is a minimally invasive kidney surgery, an operation used to treat a blockage at the junction between the kidney and the ureter (the tube that drains urine from the kidney to the bladder). This study looks at whether using a special surgical instrument called TriSect rapide®, a multifunctional device that can cut and seal tissue, can make laparoscopic pyeloplasty faster and as safe as the standard method. The goal is to relieve this blockage and improve kidney function.

Who can participate?
Adult patients (≥18 years) diagnosed with ureteropelvic junction obstruction (UPJO) who are scheduled for elective laparoscopic pyeloplasty at the participating institution.

What does the study involve?
Participants were randomly assigned to one of two groups. One group had the surgery done with the TriSect rapide®. The other group had the surgery done with standard surgical instruments.

What are the possible benefits and risks of participating?
Possible Benefits:
Participants may experience shorter operative times and reduced anesthesia exposure due to the use of a multifunctional surgical instrument. The findings may help improve surgical efficiency and patient care for future patients with ureteropelvic junction obstruction.

Possible Risks:
Standard surgical risks such as bleeding, infection, or injury to surrounding structures. Device-specific risks may include technical failure or unintended tissue effects, though these are not

expected to exceed the standard risk profile for laparoscopic pyeloplasty. Typical Anesthesia-related risks for procedures under general anesthesia. There is no anticipated increased risk due to participation in the study beyond what is expected for standard surgical treatment.

Where is the study run from?
The study was conducted with internal institutional resources. No external or commercial funding was received. The study is conducted at the Department of Urology, Hermann-Josef Hospital, Erkelenz, Germany.

When is the study starting and how long is it expected to run for?
June 2023 to July 2025

Who is funding the study?
Hermann-Josef Hospital Erkelenz, Germany
Essen University Hospital, Germany

Who is the main contact?
Dr. Christian Niedworok, Department of Urology, christian.niedworok@uni-due.de

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Prof Christian Niedworok

### ORCID ID
https://orcid.org/0000-0002-6796-9882

### Contact details
Urology Clinic of the Hermann-Josef Hospital
Tenholter Str. 43
Erkelenz
Germany
41812
+492431892747
christian.niedworok@uni-due.de

# Additional identifiers

# Study information

### Scientific Title
Prospective randomized analysis of operating time and safety of laparoscopic pyeloplasty with or without TriSect rapide® in adult patients with ureteropelvic junction obstruction

### Study objectives

This trial evaluated whether the TriSect rapide® could enhance surgical performance by reducing operative time without adversely affecting patient outcomes, quality of life, or the rate of perioperative complications, compared to standard laparoscopic instruments.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 31/07/2024, North Rhine Medical Association (Ärztekammer Nordrhein) (Tersteegenstr. 9, Dusseldorf, 40401, Germany; +4922143020; aerztekammer@aekno.de), ref: 2024105

## Primary study design
Interventional

## Study design
Prospective randomized clinical trial

## Study type(s)
Efficacy, Quality of life, Safety, Treatment

## Health condition(s) or problem(s) studied
Ureteropelvic junction obstruction (UPJO) in adult patients undergoing laparoscopic pyeloplasty

## Interventions
This was a prospective, randomized clinical trial conducted to evaluate the operative time and safety of laparoscopic pyeloplasty with or without the use of the TriSect rapide® device in adult patients with ureteropelvic junction obstruction. Patients were randomly assigned to either the intervention group (TriSect rapide®) or the control group (standard instruments). Randomisation was performed 1:1 using a computer-generated randomisation list with a block size of 4. Group allocation was conducted by an independent individual using sequentially numbered, opaque, sealed envelopes. Preoperative and postoperative parameters, surgical duration, complications, and quality of life outcomes were assessed and compared between the two groups.

Experimental group:
Laparoscopic pyeloplasty using the multifunctional energy device TriSect rapide® for dissection and hemostasis.

Control group:
Laparoscopic pyeloplasty using standard bipolar and monopolar instruments for dissection and hemostasis.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)

TriSect rapide® (Olympus Surgical Technologies Europe)

### Primary outcome(s)
Total operative time (minutes) measured using data collected from the surgical record during the operation (single surgical session) from initial incision to final skin closure

### Key secondary outcome(s)
1. Preparation time (minutes) measured using data collected from the surgical record during the operation, the time from initial trocar insertion to the beginning of the anastomosis
2. Anesthesia duration (minutes) measured using data collected from the surgical record, from induction of anesthesia to extubation
3. Intra- and perioperative complications measured using data collected from case report forms intraoperatively and during hospital stay, graded using the Clavien-Dindo classification
4. Health-related quality of life (HRQoL) measured using the RAND 36-Item Short Form Survey Instrument (SF-36) or other validated PROM preoperatively and 6 weeks postoperatively

### Completion date
31/07/2025

## Eligibility

### Key inclusion criteria
1. Confirmed UPJ obstruction
2. Aged between 18 and 80 years
3. ASA-performance status 1-3
4. Eligibility for surgical intervention
5. Life expectancy > 12 months
6. Ability to provide written informed consent and willingness to comply with scheduled follow-up visits

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
80 Years

### Sex
All

### Total final enrolment
22

### Key exclusion criteria
1. Unable or unwilling to provide informed consent
2. Pregnant patients
3. Patients under the age of 18 or over 80
4. Unfit or unwilling to undergo surgery
5. Surgery involving the retroperitoneum, ureter or kidney
6. Anticipated noncompliance with follow-up requirements
7. Chronic substance abuse
8. Insurmountable language barriers
9. Concurrent participation in another clinical study

### Date of first enrolment
01/09/2024

### Date of final enrolment
31/05/2025

## Locations

### Countries of recruitment
Germany

### Study participating centre
**University Hospital Essen**
Hufelandstr. 55
Essen
Germany
45147

### Study participating centre
**Hermann-Josef Hospital Erkelenz**
Tenholter Str. 43
Erkelenz
Germany
41812

## Sponsor information

### Organisation
University of Duisburg-Essen

### ROR
https://ror.org/04mz5ra38

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Hermann-Josef Hospital

**Funder Name**
Essen University Hospital

# Results and Publications

**Individual participant data (IPD) sharing plan**
The aggregated anonymized datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Christian Niedworok, christian.niedworok@uni-due.de, to qualified researchers upon reasonable request, subject to ethical approval and institutional agreements.

Due to data protection regulations and the absence of explicit participant consent for public data sharing, individual participant data will not be made publicly available.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 15/07/2026 | 17/07/2026 | Yes | No |