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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
11/08/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Nil known

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

Study design
Prospective randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

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

Participant information sheet
See study outputs table

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
TriSect rapide® (Olympus Surgical Technologies Europe)

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/06/2023

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
22

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

Sponsor details
Hufelandstr. 55
Essen
Germany
45147

Sponsor type
University/education

Website
https://www.uni-due.de

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

Publication and dissemination plan
The results of this study will be submitted for publication in a peer-reviewed scientific journal, regardless of whether they are positive, negative, or inconclusive. The findings will also be presented at relevant national and international urology conferences. Summaries of the results may be made available to participants upon request. In line with open science principles, anonymized data may be shared with other researchers upon reasonable request and following appropriate data protection procedures.

Intention to publish date
31/12/2025

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