Trial Description

Title

Impact of anatomical bladder neck preservation on functional and oncologic outcomes after robotic-assisted laparoscopic radical Prostatectomy

Trial Acronym

Problane

URL of the trial

[---]*

Brief Summary in Lay Language

There is a need for further optimization of continence results after robotically assisted radical prostate removal. Here, the technique of so-called anatomical bladder neck preservation could have a positive effect on improving continence. In this study, all patients are randomly assigned either to the group of the classical standard technique without planned bladder neck preservation (control group) or to the group of anatomical bladder neck preservation (test group). The hypothesis of the study is that the bladder neck preservation technique is superior to the non-bladder neck preservation technique with regarding the postoperative urinary incontinence.

Brief Summary in Scientific Language

Prospective, randomized, controlled, unicentric, superiority study comparing the bladder neck preserving with the non-bladder neck preserving technique in robotic-assisted laparoscopic radical prostatectomy for the treatment of prostate cancer regarding postoperative urinary incontinence.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

Individual participant data (text, tables, figures, annexes) will be made available after anonymisation. As further supporting date the study protocol will be provided. The data will be available 9 to 36 months after publication for scientists who submit a proposal. Proposals can be submitted up to 36 months after publication.

Organizational Data

- DRKS-ID: **DRKS00021096**

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- Date of Registration in DRKS: **2020/03/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2020-14807 , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- ICD10: **C61 - Malignant neoplasm of prostate**
- ICD10: **R32 - Unspecified urinary incontinence**

Interventions/Observational Groups

- Arm 1: **non-bladderneck preserving technique**
- Arm 2: **bladderneck preserving technique**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Recovery of urinary incontinence 3 months after surgery

Secondary Outcome

Urinary incontinence 6 and 12 months after surgery, perioperative complications, oncological outcome (TNM, R-status, recurrence, metastasis), long-term complication rates, 24h pad test, uroflow, residual urine

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Urologie, Mainz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/07/05**
- Target Sample Size: **238**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients over the age of 18 years, performance of a radical prostatectomy with confirmed prostate carcinoma, declaration of consent

Exclusion criteria

**Preoperatively pre-existing incontinence,
preoperative suspicion of a bladder neck infiltrating growth, previous surgical or radiotherapy prostate treatment, previous operations in the small pelvis, previous radiotherapy in the small pelvis, Neurogenic voiding dysfunction, urethral stricture or bladder neck stenosis (preceding or existing), ongoing neuroleptic or antidepressive therapy**

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*