Trial Description

Title

Randomized, multicenter study comparing robot-assisted and conventional laparoscopic radical prostatectomy

Trial Acronym

LAP-01

URL of the trial

[---]*

Brief Summary in Lay Language

The objective of the study is the comparison of two surgical techniques for localized prostate cancer (robot-assisted versus non-robot-assisted). Bring the robot-assisted method benefits for the patient. Analyzed are men with localized prostate cancer.

Brief Summary in Scientific Language

Robot-Assisted Laparoscopic Radical Prostatectomy compared to conventional laparoscopic radical prostatectomy in terms of functional, clinical and oncological parameters and quality of life and patient satisfaction.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00007138**
- Date of Registration in DRKS: **2014/11/13**
- 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.: **079-12-05032012 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **conventional laparoscopic radical prostatectomy**
- Arm 2: **robot-assisted laparoscopic radical prostatectomy**

Characteristics

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

Primary Outcome

continence 3 months postoperative (ICIQ=Urinary Incontinence Form, pads, diary)

Secondary Outcome

- Continence (ICIQ-SF): 1, 3, 6, 12 months p.o.
- Continence (Pads-per day): 1, 6, 12 months p.o.
- Erectile function (IIEF-5): 3, 6, 12 months p.o.
- Quality of life (EORTC QLQ-C30): 1, 3, 6, 12 months p.o.
- Anxiety and depression (HADS): 1, 3, 6, 12 months p.o.
- Satisfaction: 1, 3, 6, 12 months p.o.
- PSA: 3, 6, 12, 24, 36

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Urolgie, Düsseldorf**
- University Medical Center **Klinik für Urologie, Heidelberg**
- Medical Center **Klinik für Urologie, Dortmund**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/11/17**
- Target Sample Size: **782**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- Histologically confirmed prostate cancer (diagnosis)
- Indication for primary-curative radical prostatectomy
- Patients aged ≤ 75 years (at the time of surgery)

Exclusion criteria

- Obese patients with a BMI> 35
- Currently present severe concomitant disease (eg,
Liver cirrhosis, secondary malignancy or recurrence of any kind)
- Tumor stage: T4
- Previous malignancy (≤ 3 years before inclusion in this study)
- Neoadjuvant therapy (≤ 3 months prior to inclusion in this study)
- Immune Compromised Patients
- Intermittent self-catheterization (in the year prior consent)
- The following treatments in the past 3 months: Operations at Sigma, extensive Hämorrhoidalresektion, Transurethral needle ablation of the prostate (TUNA), osteosynthesis supplies the pelvic area, salvage prostatectomy

- Patients with chronic urinary tract infection (proven more than 5 antibiotic-requiring infection episodes in last year)
- Requiring dialysis patients

Addresses

■ **Primary Sponsor**

Universität Leipzig
Ritterstraße 26
04109 Leipzig
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Universitätsklinikum LeipzigKlinik und Poliklinik für Urologie
Ms. Dr. Sigrun Holze
Liebigstr. 20
04103 Leipzig
Germany

Telephone: **03419717600**
Fax: **[---]***
E-mail: **LAP-01 at uniklinik-leipzig.de**
URL: **[---]***

■ **Contact for Public Queries**

Universitätsklinikum LeipzigKlinik und Poliklinik für Urologie
Ms. Dr. Sigrun Holze
Liebigstr. 20
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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Deutsche Krebshilfe e.V.

Private sponsorship (foundations, study societies, etc.)

Deutsche Krebshilfe e.V.
Buschstr. 32
53113 Bonn
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

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

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.