

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Evaluating the feasibility and accuracy of novel intra-operative molecular imaging with two PSMA-tracers in prostate cancer**

### Trial Acronym

**CLI AI PSMA**

### URL of the trial

**[---]\***

### Brief Summary in Lay Language

The goal of a successful therapy in prostate cancer is the complete eradication of the tumor. Therefore it is important that during surgery tumor tissue is removed with sufficient safety margins to healthy tissue. To ensure that, frozen section analysis of excised specimens is performed during surgery. Unfortunately, this technique does not allow to inspect the complete surface of tumor specimens removed and there remains the risk that the safety margins are too small. A final judgement is only possible after postoperative histologic examination of the removed tissue. The aim of this study is to evaluate two new imaging techniques that will allow an inspection of the whole surface of removed tumor tissue during surgery (intraoperative).

### Brief Summary in Scientific Language

Prostate cancer (PCa) is a leading cause of cancer-related morbidity. In men with localized disease and a long life expectancy surgery and radiotherapy are the treatment modalities of choice. The goal of radical prostatectomy is complete eradication of cancer while preserving continence and potency. Currently surgeons have no reliable and accurate tool to intra-operatively detect cancer, which is why standard of care remains visual inspection and palpation as well as targeted frozen section analysis of excised specimen. Recently, prostate-specific membrane antigen ligand (PSMA) positron emission tomography (PET) has emerged as an accurate tool to detect PCa in both primary staging and at time of biochemical recurrence. Interestingly, PET imaging agents also emit optical photons via a phenomenon called Cerenkov luminescence. This enables optical imaging called Cerenkov Luminescence Imaging (CLI). Because the emitted photons only penetrate overlying tissues of approximately 1 mm thickness CLI is limited to detection of superficial prostate cancer cells. Similarly, a novel autoradiography imaging (AI) technique for intraoperative evaluation of tumor resection margins has been described lately for use with fluorinated PET tracers. Intraoperative radioguidance may help surgeons in the detection of extracapsular extension, positive surgical margins and lymph node metastases with the aim of increasing surgical precision and possibly improving oncological outcome.



**The objective of our project is to assess the feasibility and accuracy of novel imaging with CLI and ARI in prostate cancer surgery. Within this study we will use an interdisciplinary approach integrating imaging and pathological data in order to evaluate intra-operative molecular imaging with the two PSMA-tracers in PCa surgery. After informed consent, men with PCa and a high risk of positive surgical margins or lymph node metastases (cT3 stage or ISUP Gleason grade group 4/5 or PSA >15 ng/ml) will undergo PSMA-PET/CT with 68Ga-labelled PSMA-11 or 18F-labelled PSMA-1007 on the day of surgery. Subsequently, radical prostatectomy will be performed and excised specimen will be imaged immediately ex vivo with CLI and ARI in order to identify regions at risk for extracapsular extension of cancer and positive surgical margins.**

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

**Yes**

**Description IPD sharing plan**

**Publication of the data in professional journals**

## Organizational Data

- DRKS-ID: **DRKS00020942**
- Date of Registration in DRKS: **2020/03/30**
- 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.: **19-8749-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

## Secondary IDs

## Health condition or Problem studied

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

## Interventions/Observational Groups

- Arm 1: **Intraoperative assessment of Cerenkov luminescence using the CLI-System (Lightpoint medical Ltd., U.K.) and autoradiography imaging (AI) respectively by using a flexible scintillator and PSMA tracers (68Ga-PSMA-11/18F-PSMA 1007) in prostate cancer.**



## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **I**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Assessment of positive surgical margins in radical prostatectomy using novel intra-operative molecular imaging (CLI and AI) with PSMA-labeled radiopharmaceuticals (68Ga-PSMA-11 / 18F-PSMA 1007) as compared to final histopathology.**

## Secondary Outcome

- Compare performance of CLI±AI to frozen section analysis
- Assess positive lymph node status in CLI±AI with final histopathology
- Compare both tracers regarding lymph node status
- Evaluate the flexible scintillator in reducing background noise
- Evaluate the radiation exposure of the surgery and pathology teams
- Compare the duration of complete intra-operative imaging vs. frozen section analysis.

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Klinik und Poliklinik für Urologie, Kinderurologie und Uroonkologie, Essen**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/12/13**

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- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

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

### Additional Inclusion Criteria

- **Male  $\geq$  18 years of age**
- **Histologically confirmed adenocarcinoma of the prostate**
- **High-risk for positive surgical margins**
  - a. **cT3 stage according to TNM classification, or**
  - b. **ISUP Gleason grade group 4/5, or**
  - c. **PSA  $>$ 15 ng/ml**
- **Indication for radical prostatectomy**
- **Preoperative PCa staging performed according to current guidelines**

### Exclusion criteria

- **Known hypersensitivity to the diagnostic PET agent or its components**
- **Administration of any kind of PET tracer within a period corresponding to 8 half-lives of the respective radionuclide**
- **Subjects not able to declare meaningful informed consent on their own (e.g. with legal guardian for mental disorders)**
- **Evidence of neuroendocrine small cell prostate cancer**
- **Polytope metastases on conventional imaging as per CHARTED criteria (visceral metastases or  $\geq$ 4 bone metastases including at least one outside the axial skeleton)**

### Addresses

- **Primary Sponsor**

**Klinik und Poliklinik für Urologie, Kinderurologie und Uroonkologie  
Universitätsklinikum Essen  
Hufelandstrasse 55  
45147 Essen  
Germany**

### **Primary Sponsor**

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45147 Essen  
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### ■ **Contact for Scientific Queries**

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## **Sources of Monetary or Material Support**

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

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**Deutsches Register  
Klinischer Studien**

German Clinical  
Trials Register

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

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**Germany**

Telephone: [---]\*

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E-mail: [---]\*

URL: <https://urologie.uk-essen.de/>

## 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](#).*