

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

## Trial Description

### Title

**Prostate Cancer Outcomes - Compare & Reduce Variation in Prostate Cancer Centers certified by the German Cancer Society**

### Trial Acronym

**PCO-D**

### URL of the trial

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### Brief Summary in Lay Language

**Prostate cancer is the most common cancer of men worldwide. Treatment-related side effects include urinary incontinence, bowel problems, erectile dysfunction and psychological discomfort. It is suspected that treatment results vary heavily across the world. Prostate cancer centers from 12 countries take part at the multinational PCO study (Prostate Cancer Outcomes - Compare & Reduce variation) to compare their results and to improve care. Currently, 23 of these centers are certified by the German Cancer Society that make up the centers of this (German-speaking) sub-study. Other participating centers are located in Australia, the USA, Italy and the United Kingdom, to mention only a few countries. The participating centers systematically record clinical and patient reported outcomes (PROs) for localized prostate cancer and compare results across sites.**

**Expected results include statements regarding the quality of care in prostate cancer centers taking into account the patient's perspective, the recognition of regional / hospital-related differences and the identification of measures to improve quality in centers.**

### Brief Summary in Scientific Language

**Background: The assessment of health outcomes quality beyond survival rates is of particular importance with regard to prostate cancer, as the four most commonly applied treatment strategies (radical prostatectomy, percutaneous radiotherapy, LDR or HDR brachytherapy, active surveillance) each have specific side-effect patterns, which significantly co-vary with provider and patient/disease characteristics. In the past, numerous observational studies have investigated the advantages and disadvantages of different strategies in terms of survival and major physical side-effects such as incontinence, erectile dysfunction and bowel problems, as well as differences between clinicians. Possible psychological and social effects, such as fear of progression/recurrence of the disease or reduced participation in public life, in addition to the physical consequences of treatments are contributing to the complexity of health outcome assessments.**

**Objectives of the study: The primary objective of the study is to compare the**

**quality of health out-comes (patient-reported and clinical) in participating prostate cancer centres that have been certified according to the requirements of the German Cancer Society with each other and - in the second step - with international centres. The secondary objective of the study is the analysis of selected (and, in this form, new) methods for identifying potential pitfalls in patient inclusion and representation, in the user-friendliness of the survey tool as well as in data linking (formative evaluation of methods).**

**Methods:** In this multicentric observational study with consecutive full survey of the study population, patients with localised prostate cancer are interviewed at baseline and then periodically following therapy (follow-up to 10 years) using standardised tools. The survey data will be linked to clinical features gathered by the centres. Additionally characteristics of the centres are recorded. Statistical analysis is performed using the common descriptive and (multilevel) regression analysis methods. Health outcomes are compared case-mix-adjusted.

**Anticipated results:** Statements about the quality of care in prostate cancer centres taking into account the patient's perspective and where applicable regional/hospital-related differences. Measures to improve quality in certified centres will be taken based on the results of the study. It is anticipated that the differences in the quality of health outcomes will decrease over time as measures are introduced in less high-quality centres. Possibilities for the identification of individual measures to improve poor quality of life shall additionally be highlighted.

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

**No**

**Description IPD sharing plan**

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## Organizational Data

- DRKS-ID: **DRKS00010774**
- Date of Registration in DRKS: **2016/09/08**
- 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.: **Eth-12/16 , Ethik-Kommission der Ärztekammer Berlin**

## Secondary IDs

## Health condition or Problem studied

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

## Interventions/Observational Groups

- Arm 1: **Prostate cancer patients are surveyed pre- and posttherapeutically (EPIC-26 and additional items) to identify differences in outcomes across centers. Additional clinical parameters are collected according to study protocol**

## Characteristics

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

## Primary Outcome

**1. (relative) survival, 2. disease-free survival, 3. PROs: 3a. incontinence, 3b. irritative/obstructive, 3c. gastrointestinal, 3d. sexuality, 3e. hormonal, and 3f. libido, collected after 6 and 12 months, then annually**

## Secondary Outcome

**formative evaluation of data collection method**

## Countries of recruitment

- DE **Germany**
- CH **Switzerland**

## Locations of Recruitment

- Medical Center **Prostatakrebszentrum, Straubing**

- Medical Center **Prostatakrebszentrum, Sindelfingen**
- Medical Center **Prostatakrebszentrum, Oberhausen/Niederrhein**
- University Medical Center **Prostatakrebszentrum Martini-Klinik, Hamburg**
- Medical Center **Prostatakrebszentrum, Wolfsburg**
- Medical Center **Prostatakrebszentrum, Ludwigsburg**
- Medical Center **Prostatakrebszentrum Vinzenzkrankenhaus, Hannover**
- University Medical Center **Prostatakrebszentrum , Köln**
- Medical Center **Prostatakrebszentrum Helios, Erfurt**
- Medical Center **Prostatakarzinomzentrum am Katholischen Krankenhaus St. Johann Nepomuk Erfurt, Erfurt**
- Medical Center **Prostatakrebszentrum Hegau-Bodensee , Singen**
- Medical Center **Tübinger Prostatakrebs Zentrum, Tübingen**
- University Medical Center **Prostatakrebszentrum, Erlangen**
- University Medical Center **Prostatakrebszentrum, Ulm**
- University Medical Center **Prostatakrebszentrum, Münster**
- Medical Center **Prostatakrebszentrum St. Josef, Paderborn**
- Medical Center **Prostatakrebszentrum, Gütersloh**
- Medical Center **Prostatakrebszentrum, Dortmund-Ost**
- Medical Center **Prostatakrebszentrum, Bielefeld**
- Medical Center **Prostatakrebszentrum Sana Kliniken, Lübeck**
- Medical Center **Prostatakarzinomzentrum, Wesermünde**
- Medical Center **Klinikum Lüneburg, Lüneburg**
- Medical Center **Ammerland Klinik GmbH, Westerstede**
- Medical Center **Prostatakrebszentrum Bremen-Mitte, Bremen**
- Medical Center **Prastatakrebszentrum Neuruppin, Neuruppin**
- Medical Center **Prostatakrebszentrum Vivantes Auguste Klinikum, Berlin**
- Medical Center **Prostatazentrum im Friederikenstift, Hannover**
- University Medical Center **Urologisches Tumorzentrum MHH, Hannover**
- Medical Center **Prostatakarzinomzentrum, Braunschweig**
- Medical Center **Prostatakarzinomzentrum, Ahaus**
- Medical Center **Prostatakrebszentrum Münster-Süd, Münster**
- Medical Center **Prostatakrebszentrum Franziskus Hospital, Bielefeld**
- Medical Center **Prostatakrebszentrum Lippe, Detmold**

- Medical Center **Prostatakarzinomzentrum am Diakonissenkrankenhaus, Dassau**
- Medical Center **Prostatakarzinomzentrum im Carl-Thiem-Klinikum, Cottbus**
- Medical Center **Prostatakarzinomzentrum Martha-Maria Halle-Dörlau, Halle Saale**
- University Medical Center **Prostatakarzinomzentrums am Krukenberg-Krebszentrum Halle der Universitätsmedizin, Halle Saale**
- Medical Center **Prostatakrebszentrum Leipzig St. Georg, Leipzig**
- University Medical Center **Prostatakarzinomzentrum am Universitätsklinikum, Leipzig**
- Medical Center **Prostatakrebszentrum Sana Kliniken Leipziger Land, Borna**
- Medical Center **Prostatakarzinomzentrum am Diakonissenkrankenhaus, Dresden**
- Medical Center **Prostatakarzinomzentrum, Gera**
- Medical Center **Prostatakarzinomzentrum Zeisigwaldkliniken Bethanien, Chemnitz**
- Medical Center **Prostatakarzinomzentrum Ostvest, Datteln**
- Medical Center **ProstatakrebsZentrum, Recklinghausen**
- Medical Center **Kompetenz-Zentrum Prostatakarzinom Marienhospital, Herne**
- Medical Center **Prostatakarzinomzentrum Klinikum Dortmund, Dortmund**
- Medical Center **Lukas Prostatakrebszentrum Dortmund Süd, Dortmund**
- University Medical Center **Prostatakrebszentrum am Westdeutschen Tumorzentrum - Universitätsmedizin Essen, Essen**
- Medical Center **Prostatakarzinomzentrum der Kliniken Maria Hilf GmbH, Mönchengladbach**
- Medical Center **Prostatakrebszentrum Heilig Geist-Krankenhaus, Köln**
- Medical Center **Prostatakrebszentrum Bonn/Rhein-Sieg, Bonn**
- Medical Center **Prostatakarzinomzentrum Koblenz-Mittelrhein, Koblenz**
- Medical Center **Prostatakarzinomzentrum Klinikum Fulda, Fulda**
- Medical Center **Prostatakrebszentrum Südthüringen, Meiningen**
- Medical Center **Prostatakarzinomzentrum am Krankenhaus Nordwest, Frankfurt a.M.**
- Medical Center **Prostatakrebszentrum Klinikum Bamberg, Bamberg**
- Medical Center **Prostatakarzinomzentrum Sana Klinikum Hof, Hof**
- University Medical Center **Universitäres Prostatakarzinomzentrum Mainz, Mainz**
- Medical Center **Prostatakrebszentrum am Klinikum - Aschaffenburg, Aschaffenburg**
- University Medical Center **Prostatakrebszentrum des Universitätsklinikums Würzburg, Würzburg**
- Medical Center **Prostatakarzinomzentrum Tauber-Franken, Bad Megentheim**

- Medical Center **Prostatakarzinomzentrum Nordoberpfalz, Weiden**
- Medical Center **Prostatakarzinomzentrum St. Marien Amberg, Amberg**
- Medical Center **Prostatakarzinomzentrum Fürth, Fürth**
- Medical Center **Prostatazentrum Klinikum Worms, Worms**
- Medical Center **Prostatakarzinomzentrum Rheinpfalz, Mannheim**
- Medical Center **Prostatakarzinomzentrum Offenburg, Offenburg**
- Medical Center **Prostatakarzinomzentrum Klinikum Stuttgart, Stuttgart**
- Medical Center **Prostatakarzinomzentrum Ruit, Ruit**
- Medical Center **Interdisziplinäres Prostatakarzinomzentrum Nagold, Nagold**
- Medical Center **Prostatakarzinomzentrum Reutlingen, Reutlingen**
- Medical Center **Prostatakarzinomzentrum Villingen-Schwenningen, Villingen-Schwenningen**
- Medical Center **Prostatakarzinomzentrum Sigmaringen, Sigmaringen**
- Medical Center **Prostatakarzinomzentrum Kempten, Kempten**
- Medical Center **Prostatakrebszentrum Traunstein, Traunstein**
- Medical Center **Prostatakarzinomzentrum Region Landshut, Landshut**
- Medical Center **Prostatakarzinomzentrum St. Josef Regensburg, Regensburg**
- Medical Center **Prostatakrebszentrum St. Claraspital Basel, Basel, Schweiz**
- Medical Center **Prostatakrebszentrum Freiburg PZF HFR Freiburg - Daler-Spital, Freiburg, Schweiz**
- Medical Center **Prostatakrebszentrum am Kantonsspital Aarau, Aarau, Schweiz**
- Medical Center **Prostatakrebszentrum Kantonsspital Baden, Baden, Schweiz**
- Medical Center **Prostatakrebszentrum Hirslanden Zürich, Zürich, Schweiz**
- University Medical Center **Universitäres Prostatazentrum Inselspital Bern, Bern**
- Medical Center **Prostatakarzinomzentrum Helios Kliniken Schwerin, Schwerin**
- Medical Center **Prostatakrebszentrum Klinikum Magdeburg, Magdeburg**
- Medical Center **Prostatakarzinomzentrum am Diakonissenkrankenhaus Dessau, Dessau**
- Medical Center **Prostatakarzinomzentrum Klinikum Großburgwedel, Burgwedel**
- Medical Center **Prostatakarzinomzentrum Dresden-Friedrichstadt, Dresden**
- Medical Center **Prostatakarzinomzentrum an den Johanniter-Kliniken Bonn, Bonn**
- Medical Center **Prostatakarzinomzentrum Trier, Trier**
- Medical Center **Prostatakrebszentrum Klinikum Nürnberg, Nürnberg**
- Medical Center **Prostatazentrum Memmingen, Memmingen**

- Medical Center **Prostatakarzinomzentrum Oldenburg, Oldenburg**
- University Medical Center **Prostatakrebszentrum der Universitätsmedizin Göttingen, Göttingen**
- Medical Center **Prostatakarzinomzentrum Ingolstadt, Ingolstadt**
- Medical Center **Prostatakrebszentrum Augsburg-Schwaben, Augsburg**
- Medical Center **Prostatazentrum Ravensburg, Ravensburg**
- Medical Center **Prostatakrebszentrum Neustadt an der Weinstraße, Neustadt an der Weinstraße**
- Medical Center **Prostatakrebszentrum Krankenhaus Barmherzige Brüder München, München**
- University Medical Center **Prostatakarzinomzentrum Dresden am Universitäts KrebsCentrum (UCC), Dresden**
- Medical Center **Prostatakrebszentrum Lindenhofspital Bern, Bern**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/07/01**
- Target Sample Size: **40000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

## Inclusion Criteria

- Gender: **Male**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

## Additional Inclusion Criteria

**Patients with localized prostate cancer**

## Exclusion criteria

**insufficient language skills to fill out questionnaire**

## Addresses

- **Primary Sponsor**  
**Deutsche Krebsgesellschaft**

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**Primary Sponsor**

**Deutsche Krebsgesellschaft  
14059 Berlin  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

■ **Contact for Scientific Queries**

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■ **Collaborator, Other Address**

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E-mail: [---]\*

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■ **Collaborator, Other Address**



### **Collaborator, Other Address**

**Bundesverband Prostatakrebs Selbsthilfe**  
**53111**  
**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

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

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

**Movember Foundation**  
**8002 East Melbourne**  
**Australia**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

### **Status**

#### ■ Recruitment Status: **Recruiting ongoing**

#### ■ Study Closing (LPLV): [---]\*

### **Trial Publications, Results and other documents**

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum PCO**
- trial protocol (mandatory for transfer to Studybox) **Studienprotokoll PCO**
- Further trial documents **Studienprotokoll Englisch**
- Further trial documents **Studienprotokoll Deutsch\_Amendment 2018**
- Paper **Sibert NT, Dieng S, Oesterle A, Feick G, Carl G, Steiner T, Minner J, Roghmann F, Kaftan B, Zengerling F, Hinkel A, Beyer B, Heidenreich A, Harke N, Brehmer B, Pfitzenmaier J, Fichtner J, Neisius A, Hammerer P, Wesselmann S, Kowalski C (2019). Psychometric validation of the German version of the EPIC-26 questionnaire for patients with localized and locally advanced prostate cancer. World Journal of Urology. DOI: 10.1007/s00345-019-02949-7.**
- Paper **Roth R, Dieng S, Oesterle A, Feick G, Carl G, Hinkel A, Steiner T, Kaftan B, Kunath F, Hadaschik B, Oostdam SJ, Palisaar RJ, Koralewski M, Beyer B, Wesselmann S, Kowalski C (2020). Determinants of self-reported functional status (EPIC-26) in prostate cancer patients prior to treatment. World Journal of Urology. DOI: 10.1007/s00345-020-03097-z**
- Paper **Breidenbach C, Roth R, Ansmann L, Wesselmann S, Dieng S, Carl EG, Feick**

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**G, Oesterle A, Bach P, Beyer B, Borowitz R, Erdmann J, Kunath F, Oostdam SJ, Tsaar I, Zengerling F, Kowalski C. (2020). Use of psycho-oncological services by prostate cancer patients: A multilevel analysis. Cancer Medicine. DOI: 10.1002/cam4.2999.**

- Paper **Kowalski C, Roth R, Carl G, Feick G, Oesterle A, Hinkel A, Steiner T, Brock M, Kaftan B, Borowitz R, Zantl N, Heidenreich A, Neisius A, Darr C, Bolenz C, Beyer B, Pfitzenmaier J, Brehmer B, Fichtner J, Haben B, Wesselmann S, Dieng S. (2020). A multicenter paper-based and web-based system for collecting patient-reported outcome measures in patients undergoing local treatment for prostate cancer: first experiences. Journal of Patient-Reported Outcomes 4(56). DOI: 10.1186/s41687-020-00224-7.**

\* *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.*