Trial Description

Title

Influences of targeted exercise therapy on treatment-related side effects of hormonetherapy in prostate cancer patients

Trial Acronym

Burgdorf-Study

URL of the trial

[---]*

Brief Summary in Lay Language

**The side effects of androgen deprivation therapy in prostate cancer patients is well known. Several studies suggest that physical activity has the potential to reduce side effects and therefore improve the quality of life of these patients.
The aim of this study is to investigate if the targeted exersice training affects the strength of patients with prostate cancer receiving hormon therapy. The patients take either part in an low endurance training or an intensive resistance and endurance training throughout one year.
Further endpoints of this study are quality of life, fatigue, body composition etc.
The measurments are performed at baseline and after 3,6,9 and 12 months and after 6 and 12 months follow-up.**

Brief Summary in Scientific Language

The Burgdorf-Study is a prospective, single-center, randomized, controlled trial which examines the influence of an intensive resistancen and endurance training compared to a low intensiv endurance training on the side effects of andorgen-deprivation therapy in prostate cancer patients. The duration of the intervention is one year with a follow-up periode of one year. The primary endpoint is the strength of the lower extremities. Secondary endpoints include quality of life, fatigue, endurence, erectile dysfunction, bone pain, activity level, body composition, bine mineral density, PSA and testosterone levels. In order to observe the sustainability of the intervention, 2 follow-up measurements are planned (6 and 12 months after the intervention).

Organizational Data

- DRKS-ID: **DRKS00009975**
- Date of Registration in DRKS: **2016/02/09**
- 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.: **144/2015 , Köln - Ethikkomisscion der Deutschen**

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Ethics Approval/Approval of the Ethics Committee: **Approved**
Sporthochschule zu Köln

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Strength-endurance training: 2x per week supervised about 75min, warming-up, 7 different strength exercises (2-4 series á 8-12 repetitions at 75 % of 1RM) + impact-training, cooling-down**
- Arm 2: **Endurance: 1x per week supervised, 1x per week home-based walking program, 30-45 minutes (at 50-60 % of max heart rate)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- 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

Strength: dynamically on a isokinetic dynamometer

Measurements: Baseline, 3, 6 and 12 months, and 6 and 12 months follow-up

Secondary Outcome

Endurance with a 30/15 Test on a bicycle ergometer
Quality of life via a questionnaire (EORTC QLQ - C30 and PR25)
Fatigue via a questionnaire (MFI)
Body composition via BIA (bioelectrical impedance analysis)
erectile dysfunction via a questionnaire (IIEF)
bone pain via a questionnaire (FACT- BP)
Activity level via questionnaires (QPAQ and KAS)
BMI
BMD via DXA scan
PSA and testosterone value

Measurement timing: See primary endpoint, except bone density
BMD measurements: baseline, after 12 months and 12 months follow -up

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Prostatakarzinomzentrum , Großburgwedel**
- Doctor's Practice **Hannover Langenhagen**
- other **Urologie des MVZ (Medizinisches Versorgungszentrum), Burgdorf**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2016/02/10**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

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Minimum Age: **18 Years**

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Additional Inclusion Criteria

Prostate cancer patients who have received hormone therapy continuously at least over a period of 3 months and a maximum of 12 months. The treatment needs to be continue for at least one year. Half of the patients (n = 30) received Leuprone® , the other half (n = 30) alternative hormonal therapies.

Serum testosterone levels < 0,50ng / ml (range castration)

Age > 18

singed informed consent

Exclusion criteria

ongoing medication with tricyclic antidepressants and duloxetine (Yentreve)

WHO / ECOG performance status> 2

Planned OP

Life expectancy <6 months

All disease situations that do not allow a sporting activity, in particular:
Clinically manifest heart failure (NYHA III-IV)
Respiratory partial or global failure
Durable thrombocytopenia <10,000 / ul, for example,
Autoimmunthrombozytopenien intractable.
Congenital or acquired thrombocytopenia or any coagulation disorder.
Symptomatic CHD (possibly performing exercise ECG is recommended)
Severe intractable hypertension
Not adjustable COPD
Uncontrolled cerebral convulsions
CNS metastases
Medical or mental state that leads the investigator to not allowing the patient to participate in the study. or a legally binding signature of the consent form does

Unwillingness to storage and transfer of personal data in the context of the study protocol.

Participation in another sport-study

Addresses

- **Primary Sponsor**

Primary Sponsor

Deutsche Sporthochschule zu Köln
Am Sportpark Müngersdorf 6
50933 Köln
Germany

Telephone: **[---]***
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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Sandoz International GmbH
Industriestr. 25
83607 Holzkirchen
Germany

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

Status

- Recruitment Status: **Recruiting planned**
- 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.*