

# Progressive Resistance Training and Cancer Testis (PROTRACT) - the effect of chemotherapy on the skeletal musculature in testicular cancer patients

<b>Submission date</b> 08/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

Scientific Title

Progressive Resistance Training and Cancer Testis (PROTRACT) - Efficacy of resistance training on muscle function, morphology and inflammation in testicular cancer patients undergoing chemotherapy

## **Acronym**

PROTRACT

## **Study objectives**

1. Testicular cancer patients (TCP) undergoing chemotherapy with cisplatin, etoposide and bleomycin (BEP-treatment) experience:

- 1.1. Impaired muscular function and reduced lean body mass, but high intensity progressive resistance training (HIPRT) initiated early in the course of treatment can reverse this impairment
- 1.2. Muscular atrophy, which can be reduced by HIPRT. The potential for muscular hypertrophy is attenuated in TCP compared to a healthy control group
- 1.3. Increased systemic and local inflammation, which can contribute to the muscular deconditioning, compared to a healthy control group

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. Scientific Committees of the Copenhagen and Frederiksberg Municipalities (j.no. H-1-2010-049) approved on 28th February 2011
2. Danish Data Protection Agency (j.no. 2010-41-5118)

## **Study design**

Randomised single-blinded single-centre study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Testicular Cancer

## **Interventions**

High intensity progressive resistance training 3 times per week .

1. The STR group will receive a 9 week intervention period during the entire course of BEP treatment, followed by a 12 week training period after the course of treatment.
2. The UNT group will receive usual care for 9 weeks during the entire course of BEP treatment, but will receive a 12 week training period after the course of treatment
3. The CON group will receive a 21 week training period

## **Intervention Type**

Other

## **Phase**

Not Applicable

### **Primary outcome(s)**

Cellular muscle morphology will be assessed by muscle biopsies collected from m. vastus lateralis using the Bergstrom-technique. Muscle mean fibre area and fibre type distribution will be analysed by ATPase histo-chemistry.

The outcomes will be measured on the following time points

Baseline, before 1. cycle (0 weeks): Biopsy, Dual-emission X-ray absorptiometry (DXA) scan, strength test, blood sample, questionnaires

Before 2. cycle (3 weeks): blood sample, questionnaires

Before 3. cycle (6 weeks): blood sample, questionnaires

Post treatment (9 weeks): biopsy, DXA scan, strength test, blood sample, questionnaires

Follow up (21 weeks): DXA scan, strength test, blood sample, questionnaires

### **Key secondary outcome(s)**

1. Satellite cells and intracellular signaling molecules. Muscle biopsies are analysed for number and activation of satellite cells by immunohistochemistry and levels of protein and mRNA expression of insulin-like growth factor-1 (IGF-1) and myostatin are analysed by Western blotting and real time-polymerase chain reaction (PCR) assays respectively

2. Physical function tests- Maximum isometric quadriceps muscle strength is assessed by maximum voluntary contraction (MVC)-measurements using Good Strength-chair and maximum muscle power are evaluated by Leg Extensor Power (LEP)-measurements in Power-Rig

3. Whole Body composition including lean body mass are analysed by whole body dual-energy X-ray absorptiometry (DXA scan)

4. Systemic inflammation, lipid and glucose metabolism are evaluated by fasting blood samples. 10 ml EDTA blood samples will be taken and analysed using the enzyme-linked immunosorbent assay (ELISA)- technique for levels of circulating cytokines [C-reactive protein (CRP), tumor necrosis factor (TNF)-alpha, Interleukin (IL-6, IL-18, IL-4, IL-10)], lipid and glucose metabolism [total cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL), triglycerides, glucose and insulin]

5. Patient reported outcomes will include standardised questionnaires to evaluate health related Quality of Life (QoL) by Short Form-36 (SF-36) and EORTC QLQ-C30

### **Completion date**

31/12/2012

## **Eligibility**

### **Key inclusion criteria**

Testicular cancer patients (TCP), age 18-45, with advanced disease who are scheduled to start 3 cycles of BEP-treatment

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

45 years

**Sex**

Male

**Key exclusion criteria**

1. Other previous or concurrent malignant disease
2. Cardiovascular disease
3. Chronic disease (ie. Diabetes)
4. Hypogonadism

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

31/12/2012

**Locations****Countries of recruitment**

Denmark

**Study participating centre**

UCSF

Copenhagen

Denmark

2100

**Sponsor information****Organisation**

The Faculty of Health Sciences, Copenhagen University (Denmark)

**ROR**

<https://ror.org/035b05819>

**Funder(s)**

**Funder type**

Other

**Funder Name**

Faculty of Health Science, University of Copenhagen (Denmark)

**Funder Name**

Centre of Integrated Rehabilitation of Cancer Patients (CIRE) (Denmark)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	08/07/2014		Yes	No
<a href="#">Protocol article</a>	protocol	01/08/2011		Yes	No