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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
08/03/2011		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/03/2011	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
02/10/2017	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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 intentity 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a a patient information sheet

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, bur will recieve 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 measure

Cellular muscle morphology will be assesed 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, questionairres

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

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

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

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

Secondary outcome measures

- 1. Satellite cells and intracelluar 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 questionaires to evaluate health related Quality of Life (QoL) by Short Form-36 (SF-36) and EORTC QLQ-C30

Overall study start date

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Male

Target number of participants

45

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)

Sponsor details

Blegdamsvej 3B Copenhagen Denmark 2200

Sponsor type

University/education

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/08/2011		Yes	No
Results article	results	08/07/2014		Yes	No