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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Jesper Frank Christensen

Contact details
UCSF
Rigshospitalet, afsnit 7331
Blegdamsvej 9
Copenhagen
Denmark
2100
-
jfc@rh.regionh.dk

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

01/01/2011

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 summary

Not 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