Resistance exercise training and protein supplementation to prevent side effects of androgen deprivation therapy (ADT) in men with prostate cancer

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To investigate if a combined intervention of resistance training and protein supplementation is more effective to prevent or decrease the adverse effects of ADT on body weight and body composition in men with PC compared to training alone or usual...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50739

Source
ToetsingOnline

Brief title
Training and protein during ADT in prostate cancer

Condition

- Other condition
- Reproductive neoplasms male malignant and unspecified

Synonym
loss of muscle mass and prostate cancer

Health condition

spiermassaverlies door androgeen deprivatie therapie bij prostaatakanker

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: KWF en TIFN

Intervention

Keyword: Androgen deprivation therapy, Prostate cancer, Protein supplementation, Resistance exercise training

Outcome measures

Primary outcome

The primary study endpoint will be quadriceps cross sectional area (measured by CT) and muscle strength.

Measurements of cross sectional area and muscle strength will be performed at baseline and after 5 and 12 months

Secondary outcome

Secondary study endpoints will be body composition (body mass index, waist circumference, muscle mass, fat mass, body fat distribution), measured by anthropometrics and DEXA, physical performance, endurance capacity, level of physical activity, level of independent living, nutritional intake, HRQoL, fatigue, comorbidity, blood results, muscle characteristics, and compliance.

Measurements of body composition and physical performance will be performed at baseline and after 5 and 12 months. Questionnaires on level of physical activity and independent living, fatigue, HRQoL and comorbidity will be taken at baseline, 5, 12 and 24 months.

Blood samples will be taken at 0, 5 and 12 months. Endurance capacity

(spiroergometry) and muscle characteristics (biopsies) will be measured at 0

and 5 months.

Study description

Background summary

Due to the increase of our aging population and the advances in prostate cancer (PC) treatment, the prevalence of PC patients rises. One of the cornerstones in PC treatment is the use of androgen deprivation therapy (ADT). Unfortunately, ADT leads to unfavorable changes in body composition, decreased physical performance, fatigue and a lower health related quality of life (HRQoL). Exercise- and nutritional interventions have the potential to diminish the side effects of ADT treatment. A substantial number of studies in patients with PC undergoing ADT show positive effects of exercise training on these side effects. Moreover, studies in elderly have shown that the addition of a protein supplement can enhance the positive effects of exercise training on lean body mass, muscle strength and physical performance compared to exercise alone. However, the usual care of PC patients does not contain a combined exercise and protein supplementation program yet.

Study objective

To investigate if a combined intervention of resistance training and protein supplementation is more effective to prevent or decrease the adverse effects of ADT on body weight and body composition in men with PC compared to training alone or usual care.

Study design

Randomized placebo controlled trial with three parallel groups.

Intervention

Participants will be randomly assigned to one of the two intervention groups. The control group will be recruited separately. Both intervention groups receive high-intensity resistance exercise training under direct personal supervision (twice a week, for 60 min, during 20 weeks). After 20 weeks, the patient will be encouraged to continue regular exercise at home or in the neighbourhood. During the 20 weeks training program participants will receive a placebo or protein supplement (35 gram protein) immediately after each exercise session and every evening prior to sleep. Patients in the control group will

receive usual care.

Study burden and risks

In addition to the appointments for usual medical care, all patients will be asked to spend half a day (morning or afternoon) at 0, 5 and 12 months for measurements of body composition, physical performace, and questionaires. At 24 months all patients will be asked to spend 30 minutes on filling in questionnaires. In addition patients will be asked to fill in a food diary (3 days) and to wear an accelerometer (7 days) in the week prior to the measurements at 0, 5 and 12 months.
Risks as the result of participation in this study are minimal. There are no complications associated with the procedure of a DEXA and CT scan. The level of radiation emitted during DEXA and CT scanning is merely a fraction of that emitted during a transcontinental flight. Muscle biopsies will be taken under local anaesthesia by an experienced physician, but may cause some minor discomfort for maximally up to 24 h after completion. The discomfort is comparable to muscle soreness or the pain one has after bumping into a table. In rare conditions, the biopsy can lead to local infection or bleeding.
Patients allocated to the intervention groups are supposed to participate in a 20*week exercise program, twice a week for 60 minutes. We expect that the exercise program will have a beneficial effect on the patients* health status. As a result of the resistance type exercise training program, participants will likely experience a gain in muscle mass and strength and a healthy improvement in body composition. Depending on the baseline level of fitness, this will result in an increase in functional performance. It is possible that participants may experience muscle soreness induced by unaccustomed exercise. The ingested protein and placebo supplements are regular food substances and therefore part of the normal diet.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Men with proven PC (starting) with ADT which will be continued for at least 6 months

Exclusion criteria

- Patients who are not able to perform basic activities of daily living such as walking or patients who are suffering from other disabling comorbidity that seriously hamper physical exercise (e.g. heart failure, chronic obstructive pulmonary disease (COPD), orthopedic conditions and neurological disorders).
- Patients with allergies to whey protein or lactose intolerance
- Patients who show cognitive disorders or severe emotional instability
- Unable to speak, understand and read the Dutch language
- Estimated life expectancy < 1 year

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-09-2017
Enrollment:	208
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-10-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-03-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-09-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-10-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20332
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59282.068.16
OMON	NL-OMON20332