Krachttraining en eiwitsuppletie ter preventie van bijwerkingen van hormonale behandeling bij mannen met prostaatkanker.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20332

Source
NTR

Brief title
Training and protein during ADT in prostate cancer

Health condition

prostate cancer, androgen deprivation therapy, muscle mass, resistance exercise, protein supplementation

prostaatkanker, androgen deprivatie therapie, spiermassa, krachtttraining, eiwitsuppletie

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Dutch Cancer Society
Top Institute Food and Nutrition (TIFN)

Intervention

Outcome measures

Primary outcome

Body composition: body weight, body height, BMI, waist circumference, muscle mass, fat mass, body fat distribution assessed with DEXA and quadriceps muscle cross-sectional area measured by CT scanning of the upper leg.

Secondary outcome

Muscle strength: measured by 1-RM

„h Maximal oxygen uptake (VO2max)

„h Physical performance (timed Up and Go test, 30 seconds chair stand test, stair climbing test)

„h Level of independent living (The Impact on Participation and Autonomy (IPA) Questionnaire) (Appendix F1.2)

„h HRQoL (EORTC QLQ-C30, EORTC QLQ-PR25) (Appendix F1.3 en F1.4)

„h Fatigue (Multidimensional Fatigue Inventory (MFI) (Appendix F1.5)

„h Blood results (PSA, testosterone, LDH, alkalis phosphatase, triglycerides, cholesterol (HLD, LDL and total), glucose, creatinine, liver function)

„h Adverse events (Number, kind and seriousness)

Study description

Background summary

Rationale: 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.

Objective: To investigate if a combined intervention of resistance exercise 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 two parallel intervention groups and a separate control group.
Study population: Three groups (usual care (n=64); training with protein enriched supplement (n=72); training with placebo supplement (n=72)) of men ¡Ý 60 years with PC starting with ADT.

Intervention: Patients for the control group will be separately recruited in one hospital. Patients for the intervention groups will be recruited in two other hospitals and randomly assigned to one of the two intervention groups. 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.

Main study parameters/endpoints: The primary study endpoint will be body composition (body mass index, waist circumference, muscle mass, fat mass, body fat distribution), measured by anthropometrics, DEXA and CT scan. Secondary study endpoints will be muscle strength, maximal oxygen uptake, physical performance, level of physical activity, level of independent living, nutritional intake, HRQoL, fatigue, comorbidity and blood results. Measurements of body composition, muscle strength and physical performance will be performed at baseline and after 5 and 12 months. Participants will be asked to wear an accelerometer and to fill in a food diary in the week prior to the three measurements. Questionnaires on level of physical activity and independent living, fatigue, HRQoL, comorbidity and nutritional intake will be taken at baseline, 5, 12 and 24 months. Blood samples will be taken at 0, 5 and 12 months.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In addition to the appointments for usual medical care, all patients will be asked to spend half a day at 0, 5 and 12 months for measurements of body composition, muscle strength, physical performance, and questionnaires. In addition, participants will be asked to wear an accelerometer and to fill in a food diary for the 3 days in the week prior to the three measurements. At 24 months all patients will be asked to spend 30 minutes on filling in questionnaires.
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. Patients allocated to the intervention groups are supposed to participate in a 20¨Cweek 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.

Study objective

1. Training will lead to less gain in fat mass, a better body fat distribution and less loss of muscle mass compared to usual care.

2. Training will lead to an increase in muscle strength, a higher level of physical performance, independent living and HRQoL and less fatigue.

3. Participants in the combined training - protein supplementation group will have an additional positive effect on muscle mass, muscle strength, physical performance, the level of independent living, HRQoL and fatigue compared to participants in the training ¡§C placebo supplementation group.

Study design

baseline (before start training), and 5 and 12 months after start ADT.

Intervention

3 arms:

- control group that receives usual care

- intervention group that receives 20 weeks of resistance exercise plus protein supplements

- intervention group that receives 20 weeks of resistance exercise plus placebo supplements

Contacts

Public
School of Nutrition and Translational Research in Metabolism (Nutrim)

Milou Beelen
P.O. Box 616

Maastricht 6200 MD
The Netherlands
T +31 (0)43 3881394
Scientific

School of Nutrition and Translational Research in Metabolism (Nutrim)

Milou Beelen
P.O. Box 616

Maastricht 6200 MD
The Netherlands
T +31 (0)43 3881394

Eligibility criteria

Inclusion criteria

Men with PC on ADT for progressive disease (metastatic disease or increasing PSA level after primary treatment)

Exclusion criteria

- Allergies to whey protein

- Lactose intolerance

- High risk of fractures

- 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 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)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2017
Enrollment:	208
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50739
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6258
NTR-old	NTR6432
CCMO	NL59282.068.16
OMON	NL-OMON50739

Study results