SUPERvised three-month exercise program in MEN with Prostate cAncer Receiving androgen-deprivaTioN thERapy

Published: 29-11-2022
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To examine the impact of a supervised training program on disease-related quality of life and physical fitness in patient with advanced prostate cancer compared to usual care.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON53736

Source
ToetsingOnline

Brief title
SUPERMAN-PARTNER

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Genitourinary tract disorders NEC

Synonym
Prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: subsidie van het ziekenhuis (CWZ)

Intervention

Keyword: ADT, physical fitness, prostate cancer, quality of life

Outcome measures

Primary outcome

Primary objective: To examine the impact of a supervised training program on disease-related quality of life in patient with advanced prostate cancer compared to usual care.

Secondary outcome

Secondary objective: Assessment of the effectiveness of a supervised training program on cardiopulmonary fitness and body composition in patients with metastatic prostate cancer compared to usual care.

Study description

Background summary

Past decades, the incidence of prostate cancer has more than tripled with a prevalence of nearly 90.000 men in the Netherlands. Fifteen percent is primarily diagnosed with advanced prostate cancer. Androgen Deprivation Therapy (ADT) is the cornerstone treatment for these patients. However, treatment exposes patients to a host of important adverse effects such as loss of quality of life, loss of physical fitness, decrease in muscle and bone mass and psychological complaints. In addition, patients experience direct negative effects of the bone metastasis such as fatigue, (bone) pain, hypercalcaemia and pathological fractures. In patients with localized prostate disease, a structured, supervised training program is an effective and safe method to improve quality of life and physical functioning. In vivo research suggests that physical activity may slow progression of osseous metastatic disease. Therefore, a structural training program is seen as potentially effective and meaningful adjuvant therapy in patients with metastatic prostate carcinoma with an improvement in physical fitness, disease-related quality of life and an increase in muscle and bone mass.

Study objective

To examine the impact of a supervised training program on disease-related quality of life and physical fitness in patient with advanced prostate cancer compared to usual care.

Study design

Patients will be recruited by invitation of their cancer specialist (urologist) who will provide clinically eligible patients with a study information sheet and refer these patients to a study coordinator (sport physician).

In a single blinded (investigators blinded to group allocation) randomized controlled pilot, conducted in the CWZ, 20 patients with advanced prostate cancer will be randomized across: 1) supervised training program for twelve weeks + usual care, or 2) usual care.

Intervention

Supervised training program: The training program will be set at the hospital under the supervision of a physiotherapist. The intervention will consist of combined aerobic and resistance training twice a week for 3 months (12 weeks). In addition, patients are advised to walk or cycle for at least half an hour a day.

Study burden and risks

It will be a burden in particular in terms of time. Patients must come to the hospital twice a week for a supervised exercise. It has already been shown in the literature that this patient population can safely participate in physiotherapy.

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

Signed informed consent
Age > 18 years old
Able to read and complete questionnaires in Dutch
Proven histologically and /or radiologically metastatic prostate cancer (TxNxM1)

Exclusion criteria

Other cancers
Clinicians* judgement
Age >80 years old or not able to walk 400m
Structural exercise (moderate-intensity exercise more than 150 minutes a week) during the past 3 months
Musculoskeletal, cardiovascular, or neurological disorders that could inhibit them from exercising
Spinal cord compression, history of pathological fractures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-09-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL80355.091.22