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Impact of physical exercises on inflammatory markers, fatigue, quality of life in prostate cancer men

Submission date
05/11/2015

Recruitment status
No longer recruiting

Registration date
17/11/2015

Overall study status
Completed

Last Edited
12/05/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cancer related fatigue (CRF) is the most common side effect of cancer treatment. Like many other cancer patients, people having radiotherapy (RT) for prostate cancer (PCa) can suffer from CRF. This hampers their ability to do things and affects them psychologically, leading to a decrease in quality of life (QoL). RT can lead to the release of cytokines, small proteins thought to play a role in triggering the immune system, that could play a role in an antitumour immune response. In the meantime, physical exercise can trigger an anti-inflammatory (immune) response in healthy people. Previous studies have shown that physical exercise can be beneficial to cancer patients during RT, leading to improvements in fitness, muscle strength and QoL. However, it is not known how physical exercises affect the immune system in PCa patients. This study is looking at the effect of supervised physical exercise on inflammatory blood markers (substances in the blood to measure how the immune system is responding) and how this affects PCa patients ability to do things, CRF and QoL when being treated with RT hormonal therapy (ADT).

Who can participate?
Men aged 18-75 with prostate cancer and about to start ADT.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (exercise group) are asked to do supervised moderately intense physical exercise 5 days per week. The sessions include a 5 minute warm up followed by 45 minutes of physical exercise and finishing with a 5 minute relaxation period. The exercise program starts before the RT treatment begins and then continues during the treatment. Participants in group 2 (usual care group) perform their own daily physical activity at home and are asked not to begin any formal physical exercise program. Assessments on all participants are performed before RT begins, than after 8 weeks and finally again after 10 months; these include measuring the effects of the physical exercise, and its effects on patients ability to do things, CRF, QoL and blood inflammation markers such as cytokines.

What are the possible benefits and risks of participating?
Possible benefits include improvement in QoL, CRF and general fitness. There aren't any risks associated with taking part.

Where is the study run from?
Greater Poland Cancer Centre (Poland)

When is the study starting and how long is it expected to run for?
January 2013 to August 2015

Who is funding the study?
Greater Poland Cancer Centre (Poland)

Who is the main contact?
Dr Katarzyna Hojan

Contact information

Type(s)
Scientific

Contact name
Dr Katarzyna Hojan

Contact details
Garbary St.15
Poznan
Poland
61-866

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Impact of physical exercises on inflammatory markers, fatigue, quality of life in prostate cancer men: a 12-month follow-up study

Study objectives
Cancer patients, including men with prostate cancer, have a high level of interest in lifestyle changes and are a receptive population for physical activity intervention, which, if continued

during and after cancer treatment, may have long-term general health benefits in this population of men. We hypothesize that the beneficial effects of exercises interventions on decrease of fatigue and improvement QoL may in part, be due to a reduction in chronic inflammation (blood markers).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Bioethical Committee at the Poznan University of Medical Sciences, 05/01/2012, ref: UMP No10/2012

Study design
Interventional open randomized controlled clinical trial

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 patient information sheet

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
1. Supervised physical exercise program:
The patients in the exercise group (EG) performed moderate-intensity physical exercise 5 days per week. The study exercise program began before radiotherapy (RT) with aerobic and resistance exercises to evaluate the effects of RT and hormonal therapy (ADT) prior to the initiation of training. The physical activities were completed either alone or in groups and took place at the Rehabilitation Ward in the cancer centre (hospital) under the supervision of at least one physiotherapist. Optional exercises included brisk walking, running indoors or on a treadmill, and various cycling activities (30 minutes) and 15-minute resistance exercises (2 sets of 8 repetitions of 5 different exercises: bicep curl, tricep extension, leg extension, leg curl, abdominal crunch) at 70% to 75% of their estimated one-repetition maximum (1RM). All activities lasted approximately 50 – 55 minutes. The workout consisted of a 5-minute warm-up and 45 minutes of physical exercise, followed by a 5-minute relaxation period. The physical activity was moderate, with a maximal heart rate of 65–70% (220 – age), according to American Cancer Society recommendations. The study's organizers verified the patients’ exercise programs through physical activity notebooks that were checked by a physician in the rehabilitation department once a week.

2. Usual care:
The patients in the usual care group (UG) performed their own daily physical activity at home. Patients in this group were given standard advice regarding daily physical exercises. Patients randomized to the UG were instructed not to begin any formal physical exercise programs.

Intervention Type
Behavioural

Primary outcome measure
1. Efficacy of physical exercises (data from questionnaires)
2. Blood inflammation markers
3. Assessment of functional capacity, fatigue and QoL during PCa treatment

They are measured before radiotherapy (baseline), after 8 weeks, and after 10 months (12 month follow-up).

Secondary outcome measures
Correlation (the relationship) between changes in inflammatory parameters with fatigue and QoL scores.

Overall study start date
01/01/2013

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Aged between 18 and 75 years
2. Scheduled ADT (LH-analogue 10.8 mg every 3 months) planned to continue for a total period of 36 months (3 to 5 months prior to RT, during and after completion)
3. RT received a total dose of 76 Gy in 38 fractions (in the first phase of therapy, the pelvic lymph nodes along with the prostate gland and seminal vesicles were subjected to a dose of 46 Gy at 2 Gy fractions and in the second phase of therapy the irradiated volume was limited to prostate gland plus seminal vesicles to a total dose of 76 Gy),
4. Good general condition (Eastern Cooperative Oncology Group - ECOG- performance status 0-1)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
100

Total final enrolment
72

Key exclusion criteria
1. Distant metastases and/or disease progression resulting in RT or the introduction of chemotherapy
2. Insufficiently controlled arterial hypertension or cardiac diseases resulting in circulation failure (above Stage II Heart Failure according to the New York Heart Association)
3. Insufficiently controlled metabolic diseases, endocrinological, rheumatic, and absorption disorders
4. Other tumours

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
Poland

Study participating centre
Greater Poland Cancer Centre
Garbary Street 15
Poznan
Poland
61-866

Sponsor information

Organisation
Greater Poland Cancer Centre

Sponsor details
Garbary St.15
Poznan
Poland
61-866

Sponsor type

Hospital/treatment centre

Website
www.wco.pl

ROR
https://ror.org/0243nmr44

Funder(s)

Funder type
Not defined

Funder Name
Greater Poland Cancer Centre - hospital

Results and Publications

Publication and dissemination plan
We are planning to publish the results in November 2015

Intention to publish date
30/11/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/01/2017	12/05/2021	Yes	No