

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/05/2021	Condition category Cancer	<input type="checkbox"/> 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

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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

ROR

<https://ror.org/0243nmr44>

Funder(s)

Funder type

Not defined

Funder Name

Greater Poland Cancer Centre - hospital

Results and Publications

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?
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[Results article](#)

10/01/2017

12/05/2021

Yes

No