Evaluation of heart function after physical activity during adjuvant chemotherapy in breast cancer patients

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21174

Source
NTR

Brief title
Pact-Paces-Heart study

Health condition

Breast cancer, cardiotoxicity, physical exercise

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU) in collaboration with the Nederlands Cancer Institute (Antoni van Leeuwenhoek)
Source(s) of monetary or material Support: KWF kankerbestrijding

Intervention

Outcome measures

Primary outcome

1. Extracellular volume fraction (ECV)as detected with cardiac MRI using quantitative mapping techniques.

Secondary outcome

1. Cardiac MRI parameters other than ECV; such as LVEF and global longitudinal strain

2. Cardiopulmonary exercise testing (CPET) parameters, including VO2 peak

3. Resting echocardiography

4. Stress echocardiography (post-exercise)

5. Endothelial function, as measured by the EndoPAT.

6. Muscle strength

7. Congitive functioning incl. self-reported cognitive complaints

8. Biochemical measurements regarding exercise-related and cardiovacular toxicity biomarkers

9. Quality of life, depression and anxiety, fatigue

Study description

Background summary

The Pact-Paces-Heart study

Evaluation of heart function after physical activity during adjuvant chemotherapy in breast cancer patients: a follow-up of two randomized clinical trials

Rationale for the study:

The population of breast cancer survivors is growing rapidly as a result of aging of the population and ongoing successes in cancer treatment. Nevertheless, cancer treatment can have adverse cardiovascular side effects that impact morbidity and mortality, reducing overall quality of life of cancer survivors. While accumulating evidence suggests that physical activity during cancer treatment can be a safe, non-pharmalogical approach to migitage the cardiotoxic effects of cancer treatment, this has not been demonstrated in a large population of mid-term cancer survivors.

Aim:

To explore if participation in an exercise program during adjuvant chemotherapy for breast cancer therapy has beneficial effects cardiovascular toxicitity (primary outcome), cognitive functioning, exercise capacity, endothelial function, biochemical measurements of cardiovascular toxicity, muscle strength, quality of life, fatigue and depression (secondary outcomes).

Study design:

Follow-up study of two previous RCTs (the PACT and PACES study)

Study population:

Participants of the previous PACT and PACES study; breast cancer survivors who underwent adjuvant chemotherapy 6 years ago. The estimated study population is 180 participants.

Study procedures:

Participants will be invited for a study visit to undergo a series of tests, including cardiac MRI, rest and stress echocardiography, CPET, muscle test and the assessment of endothelial function. In addition, venous blood sample will be drawn. Participants will be asked to complete an online cognitive test battery and online questionnaires concering fatigue (MFI), depression and anxiety (HADS), quality of life (EORTC QLQ30), physical activity (PASE/SQUASH), self-reported cognitive complaints (MDASI) and the presence of cardiovascular risk factors.

Study objective

We hypothesize that participation in an exercise program during adjuvant chemotherapy has reduced cardiovascular toxicity toxicity in women wiht breast cancer after an average follow-up of 6 years. In addition to cardiovacular toxicity, we hypothesize that participation in an exercise program has beneficial effects on fatigue, exercise capacity, quality of life, cognitive functioning and muscle strength.

Study design

Cross-sectional analysis; 1 time point.

Intervention

The Pact-Paces-Heart study has no interventions.

However, the previous PACT and PACES study both had interventions. In PACT, participants were randomized to an intervention or control arm. The invervention group underwent an 18 week supervised exercise program during adjuvant treatment, which started within six weeks after diagnosis. The control groups received care as usual. In contrast to PACT, PACES had two intervention arms and a control group. The first was Onco-Move, a low-intensity home-based exercise program. The second, On-Track, was high-intensity supervised exercise program. Control group received, comparable to PACT, care as usual.

Contacts

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Eligibility criteria

Inclusion criteria

Patients who participated in the previous PACT or PACES study (PACT = NTR2138, PACES = NTR2159).

Both studies investigated the effects of exercising during adjuvant chemotherapy for breast cancer using comparable exercise interventions.

Exclusion criteria

- Participants who died during follow-up

- Participants who are not considered eligible by their treating physician, based on psychological or physiological contraindications.

- Participants treated with chemotherapy, targeted therapy or thoracic radiotherapy after the completion of the original PACT or PACES trial for recurrent breast cancer (incl. contralateral breast cancer), metastases or a secondary malignancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2018
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50246

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7042
NTR-old	NTR7247
CCMO	NL64685.041.18
OMON	NL-OMON50246

Study results

Summary results
PACT:
Travier N, Velthuis MJ, Steins Bisschop CN, van den Buijs B, Monninkhof EM, Backx F, Los M, Erdkamp F, Bloemendal HJ, Rodenhuis C, de Roos MA, Verhaar M, ten Bokkel Huinink D, van der Wall E, Peeters PH, May AM. Effects of an 18-week exercise programme started early during breast cancer treatment: a randomised controlled trial.
BMC Medicine. 2015;13:121

PACES:
van Waart H, Stuiver MM, van Harten WH, Geleijn E, Kieffer JM, Buffart LM, de Maaker-Berkhof M, Boven E, Schrama J, Geenen MM, Meerum Terwogt JM, van Bochove A, Lustig V, van den Heiligenberg SM, Smorenburg CH, Hellendoorn-van Vreeswijk JA, Sonke GS, Aaronson NK. Effect of Low-Intensity Physical Activity and Moderate- to High-Intensity Physical Exercise During Adjuvant Chemotherapy on Physical Fitness, Fatigue, and Chemotherapy Completion Rates: Results of the PACES Randomized Clinical Trial. J Clin. Oncol. 2015; 33(17):1918-27