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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21174

Bron
NTR

Verkorte titel
Pact-Paces-Heart study

Aandoening

Breast cancer, cardiotoxicity, physical exercise

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU) in collaboration with the Nederlands Cancer Institute (Antoni van Leeuwenhoek)
Overige ondersteuning: KWF kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Cross-sectional analysis; 1 time point.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-05-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50246
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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