The impact of caloric restriction versus exercise on tumor and muscle tissue protein synthesis rates in breast cancer patients

Gepubliceerd: 07-10-2020 Laatst bijgewerkt: 18-08-2022

It is hypothesized that both caloric restriction and exercise lower tumor tissue protein synthesis rates but that exercise, as opposed to caloric restriction, will prevent a concomitant decline in muscle tissue protein synthesis rates.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25682

Bron
Nationaal Trial Register

Verkorte titel
CREX

Aandoening

Breast Cancer

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Tumor tissue protein synthesis rates over the 7-day intervention period in breast cancer patients.
2. Muscle tissue protein synthesis rates over the 7-day intervention period in breast cancer patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Subjects will be randomly assigned to undergo 7 days of either caloric restriction, an exercise program, or standard treatment. The caloric restriction group will undergo a 30% reduction in daily energy intake (~500-600 kcal). The exercise group will increase daily energy expenditure by 30% (~500-600 kcal) by performing 1 h of combined resistance- and endurance-type exercise and 30 min of walking. Patients following standard treatment will act as the control group. All subjects will ingest small amounts of deuterium oxide ($2H_2O$) throughout the 7-day period. The 7-day period will end with the tumor resection surgery, during which a tumor tissue sample, skeletal muscle sample, and plasma sample will be collected. Protein will be isolated from the tissue samples and analyzed for the increase in 2H-alanine enrichment to determine average tumor and muscle tissue protein synthesis rates over the 7-day assessment period (in %/d).

Doel van het onderzoek

It is hypothesized that both caloric restriction and exercise lower tumor tissue protein synthesis rates but that exercise, as opposed to caloric restriction, will prevent a concomitant decline in muscle tissue protein synthesis rates.

Onderzoeksopzet

0 days, 7 days

Onderzoeksproduct en/of interventie

1) dietary energy restriction (-30% from habitual intake), 2) daily exercise (30 min cycling at 70% HRmax, 30 min full body resistance-type exercise, 30 min walking).

Contactpersonen

Publiek

Maastricht University
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Female
2) BMI 20-35.0 kg/m2
3) Diagnosed with breast cancer, with treatment requiring a lumpectomy or mastectomy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Patients receiving preoperative chemo- or radio-therapy
2) >5% weight loss in the previous 6 months
3) Fasting glucose >7 mmol/L
4) Musculoskeletal injuries (which may interfere with performing the exercise program)
5) Participation in structured resistance exercise program
6) A history of neuromuscular problems
7) Use of anti-coagulants
8) Use of protein and/or fish-oil supplements
9) Participation in a 2H2O study in the previous 6 months

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8958
Ander register	Maastricht University Medical Center+ METC : METC 20-040

Resultaten