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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25682

Source
Nationaal Trial Register

Brief title
CREX

Health condition

Breast Cancer

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Differences between intervention groups in concentrations of circulating anabolic hormones (e.g., estrogen, insulin, growth hormone), growth factors (e.g., IGF-1, IGFBP-1, IGFBP-3), and (pro- and anti-inflammatory) cytokines (e.g., C-reactive protein, IL-1, IL-6, TNF-alpha, IL-10).

Study description

Background summary

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 (2H2O) 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).

Study objective

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.

Study design

0 days, 7 days

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	45
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-10-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8958

Register	ID
Other	Maastricht University Medical Center+ METC : METC 20-040

Study results