ISRCTN10851800 https://doi.org/10.1186/ISRCTN10851800

Effect of moderate physical exercise on the immune system in patients with breast cancer receiving preoperative chemotherapy

Submission date 20/05/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 17/06/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/06/2026	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Breast cancer patients who receive chemotherapy before surgery may have changes in how their immune system works. Moderate physical activity is thought to support the immune system, but it is not yet clear how this works during cancer treatment. This study aims to find out whether taking part in regular moderate exercise can change immune system activity in patients receiving chemotherapy before surgery. The researchers will look at changes in immune cells and proteins in the blood and explore how these relate to treatment and recovery.

Who can participate?

Participants are women aged 18 years or older with breast cancer who are suitable for chemotherapy before surgery and who are able to give written informed consent. People who are not suitable for preoperative chemotherapy or who cannot provide consent cannot take part.

What does the study involve?

Participants continue to receive their usual cancer care. In addition, they take part in a programme of moderate physical activity, such as Nordic walking, during the weeks before surgery. This involves around three sessions per week, each lasting about 60 minutes, over a period of about 9 to 10 weeks. Blood samples are taken at several time points before, during and after treatment and surgery to measure changes in the immune system. These include samples taken before chemotherapy, before starting exercise, just before surgery, shortly after surgery, and about 6 months after treatment.

What are the possible benefits and risks of participating?

Taking part in moderate exercise may help support general health and could improve how the immune system responds during treatment, although this is not guaranteed. The information collected may help improve understanding of how exercise affects cancer treatment in the future. Possible risks include tiredness or minor discomfort from exercise and brief discomfort or bruising from blood samples.

Where is the study run from?
The study is run from hospital centres in Italy, with coordination by Azienda Ospedaliera S. Croce e Carle di Cuneo.

When is the study starting and how long is it expected to run for?
July 2019 to February 2024.

Who is funding the study?
Azienda Ospedaliera S. Croce e Carle di Cuneo (Italy)

Who is the main contact?
Dr Ornella Garrone, ornella.garrone@gmail.com

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Ornella Garrone

ORCID ID
https://orcid.org/0000-0001-7359-5410

Contact details
via f. sforza 28
Milano
Italy
20122
0255032660
ornella.garrone@gmail.com

Additional identifiers

Study information

Scientific Title
NEO-RUNNER: a multicentre, non-profit, interventional, non-drug translational study evaluating the effect of moderate physical exercise on cellular and cytokine immune profiles in patients with operable breast cancer receiving neoadjuvant chemotherapy

Acronym
NEO-RUNNER

Study objectives
The NEO-RUNNER study aims to evaluate the effect of moderate physical exercise on immune system modulation in patients with operable breast cancer receiving preoperative chemotherapy.

The rationale for the study is based on the hypothesis that moderate physical activity performed during neoadjuvant treatment may influence cellular and cytokine immune profiles, contributing to a better characterization of the host biological response during therapy.

The study therefore aims to describe changes in prospectively collected immunological parameters, including peripheral blood samples and PBMCs, and to assess their association with patients' clinical and treatment-related characteristics. Any additional biological analyses not specified as primary endpoints in the protocol will be considered exploratory.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/06/2020, Comitato Etico Interaziendale A.O. S. Croce e Carle di Cuneo – ASL CN1 – ASL CN2 – ASL AT (Via Monte Zovetto, 18, Cuneo, 12100, Italy; +39 0171 641571; comitato.etico@ospedale.cuneo.it), ref: 101-2020

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Basic science, Translational study evaluating immune modulation induced by moderate physical activity during neoadjuvant chemotherapy in breast cancer patients.

Study type(s)

Health condition(s) or problem(s) studied
Breast cancer

Interventions
The NEO-RUNNER study is a prospective observational study evaluating patients with operable breast cancer who are candidates for preoperative chemotherapy.

Participants will perform a moderate physical exercise programme during neoadjuvant treatment.
Treatment/intervention duration: 9–10 weeks of moderate physical activity through Nordic Walking in the weeks preceding surgery. The intervention includes 3 training sessions per week, each lasting approximately 60 minutes. The last training session is planned between 24 and 72 hours before surgery.

Follow-up duration: study assessments include serial blood samples up to approximately 6 months after completion of chemotherapy.
Overall study duration: 24 months for patient enrolment and 12 months for follow-up and data analysis, starting from Ethics Committee approval.

No randomisation is planned and no placebo or control intervention is included. Physical exercise does not replace or modify standard oncological treatment, which will be decided according to routine clinical practice.

Clinical, treatment-related and biological data will be collected during the study. Peripheral blood samples will be obtained for the assessment of immunological parameters, including cellular and cytokine profiles, and for PBMC collection. The observations will aim to describe immunological changes over the course of treatment and their association with patients' clinical and treatment-related characteristics.

Intervention Type
Behavioural

Primary outcome(s)
1. Cellular and cytokine immune profile measured using Flow cytometry for circulating immune cell populations; commercially available ELISA/cytokine assay kits for cytokines and interleukins; complete blood count and LDH according to local laboratory procedures at T0: before the start of chemotherapy; T1: before the start of exercise training; T2: the day before surgery; T3: 48–72 hours after surgery; T4: approximately 6 months after completion of chemotherapy

Key secondary outcome(s)
1. Association between immune profile changes and clinical outcomes measured using Correlation between changes in cellular and cytokine immune parameters and disease-free survival and overall survival, using clinical data extracted from medical records and hospital databases at During follow-up, up to 12 months after completion of patient enrolment and according to available clinical follow-up data

Completion date
20/02/2024

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Female patients with breast cancer eligible for preoperative chemotherapy
3. Written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Female

Total final enrolment
99

Key exclusion criteria
1. Patients not eligible for preoperative chemotherapy
2. Inability to provide written informed consent

Date of first enrolment
11/07/2019

Date of final enrolment
02/03/2023

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Azienda Sanitaria Ospedaliera S.Croce e Carle Cuneo

ROR
https://ror.org/03pz7fw94

Funder(s)

Funder type

Funder Name
Azienda Ospedaliera S. Croce e Carle di Cuneo

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2 Milano	25/12/2021	21/05/2026	No	Yes
Participant information sheet	in Italian version 1.0 Cuneo	05/06/2020	21/05/2026	No	Yes
Protocol file	version 1	05/06/2020	20/05/2026	No	No
Protocol file	version 2	15/09/2021	20/05/2026	No	No