Informed Consent for the Patient

Study Title:

Metabolic Parameters and Quality of Life in Women Undergoing Neoadjuvant/Adjuvant Therapy for Breast Cancer: a Randomized Controlled Clinical Study on the Effectiveness of an Intensive Dietary Intervention

Dear Madam,

we would like to invite you to participate in a clinical study evaluating the effectiveness of an intensive dietary regimen, which will involve approximately 120 patients at our institution.

Participation in this research is voluntary. You may refuse to participate or withdraw at any time without losing any benefits or rights to which you are otherwise entitled. You or your legal representative will be promptly informed if new information arises that may affect your willingness to continue participating in the study. If you decide to withdraw, the study doctor or a staff member may ask you to report any medical issues that may have caused your decision to discontinue.

What is the purpose of this research?

The aim of the study is to answer the following scientific questions:

- - Primary objective: To evaluate whether an intensive dietary regimen, compared to standard recommendations, is less associated with weight gain caused by preventative therapies (chemotherapy and hormone therapy) administered to reduce the risk of cancer recurrence.
- - Secondary objectives: To evaluate the effect of the dietary regimen on:
    - Body Mass Index (BMI)
    - Body composition and basal metabolism
    - Blood metabolic profile (cholesterol, triglycerides, etc.)
    - Quality of life
    - Chemotherapy-related side effects
    - Progression-free survival
    - Overall survival

What does participation involve?

The study includes two groups: A and B. All patients will receive nutritional counseling before beginning medical therapy (chemotherapy/hormone therapy).
The difference lies in the frequency of nutritional follow-ups:
- Group A: Monthly nutritional visits for the first 6 months, then every 3 months up to 2 years.
- Group B: A single nutritional visit before therapy, one at the end of therapy (~6 months), then every 6 months for 2 years.

Assignment to a group will be randomized. The study doctor will inform you of your group assignment.

You will be asked to complete two questionnaires: one about your well-being and one about dietary adherence.

Will biological samples be collected?

Yes. Blood samples (about 10 ml) will be taken to assess metabolic parameters. Samples will be labeled with a patient code, not your name.

What procedures will you undergo?

- Blood sampling (10 ml): for metabolic variables.
- Regular medical visits: to assess weight, height, waist and hip circumference.
- Body composition analysis
- Basal metabolism test: via indirect calorimetry.
- Questionnaires: assessing dietary adherence, physical activity, side effects, and quality of life.

Privacy Protection

Your personal and sensitive data, including health information, will be handled confidentially, in accordance with Italian Personal Data Protection Law (Legislative Decree 196/2003) and relevant GDPR principles.
Only coded data will be used, and only authorized study staff will be able to link your code to your identity.

Contact Information

For more information or assistance, contact Prof. Grazia Arpino at 0817463772 / 0817463660.

Consent to Participate

To participate, you or your legal representative must sign the consent form provided (Annex 1).

Annex 1: CONSENT FORM

Study Title: Metabolic Parameters and Quality of Life in Women Undergoing Neoadjuvant/Adjuvant Therapy for Breast Cancer: a Randomized Controlled Clinical Study on the Effectiveness of an Intensive Dietary Intervention

To participate in this study, you (or your legal representative) must sign and date this form.

By signing this form, you declare that:

- You have read, understood, and had sufficient time to consider the information contained in the "Patient Consent".
- You have received clear explanations from the principal investigator and staff in response to any questions you had.
- You voluntarily agree to participate in this study, to follow the study procedures, and to provide the necessary information as requested.
- You are aware that you may withdraw your participation at any time.
- You authorize the research staff at the participating center to process your personal, common, and sensitive data related to this study, according to Article 23 of Legislative Decree No. 196 dated 30/06/2003, within the limits and in the manner specified in the Privacy Notice (Annex 1).
- You have received a copy of the "Informed Consent for the Patient".

_____ _____

Full Name of Patient Patient Number

_____ _____

Patient's Signature Date

_____ _____

Full Name of Investigator Date

_____

Signature of Investigator

INFORMATION NOTICE FOR PERSONAL DATA PROTECTION

The clinical trial center DAI Clinical and General Surgery Medicine, of the Federico II University Hospital, in accordance with responsibilities under Good Clinical Practice regulations (Legislative Decree No. 211/2003), will process your personal data to ensure confidentiality and protection, in compliance with the Personal Data Protection Law (Legislative Decree No. 196, 30/06/03).

Any personal, common, or sensitive information about you (name, initials, personal or clinical data, or lifestyle-related information) will be processed solely for: 1) supporting study objectives, 2) improving understanding of the studied condition, 3) improving future study designs.

The data specified in the protocol will be collected by the study center staff and entered into electronic data collection forms. You may obtain information about persons or companies involved in processing your data by contacting the Principal Investigator, Prof. Grazia Arpino.

Processing your personal data, including health and lifestyle information, is essential for study participation. If you refuse data access, you will not be able to participate in the study.

Nature of the Data

You will be identified by a code. The data collected during the study, excluding your name, initials, and full date of birth, will be stored with this code. Only the local investigator and designated staff can match this code with your identity.

Data Processing Methods

Your data, possibly processed electronically, will be disclosed externally only in fully anonymous form. Participation implies that, in accordance with clinical trial regulations, your data may be accessed by the pharmaceutical company personnel (or its delegates), ethics committee members, and national/international health authorities to verify data accuracy.

These checks will be conducted with due confidentiality. Scientific publications or presentations will use aggregated and anonymized data.

Exercise of Rights

You may at any time exercise your rights under Article 7 of the Code (e.g., access, correct, update your data, or object to processing for legitimate reasons) by contacting the Principal Investigator at the study center. Some data may be inaccessible until the study ends to preserve its integrity.

You may withdraw at any time without justification. Any previously collected identifiable samples will be destroyed. No new data will be collected, though prior analysis results will still be used for study purposes.

By signing this consent form, I authorize the processing of my personal data for research purposes, within the limits and according to the methods indicated in the privacy notice.

_____ _____

Full Name of Patient Patient Number

_____ _____

Patient's Signature Date

_____ _____

Full Name of Investigator Date

_____

Signature of Investigator