Study to Evaluate Impact® as Support to Anti PD1 or Anti PD1 Based Regimen Treatment in Patients With Inoperable Locally Advanced or Metastatic Melanoma

NCT06880198

Status	RECRUITING
Phase	Not Applicable
Sponsor	Fondazione Melanoma Onlus
Enrollment	20 participants

Plain Language Summary

This study tests a nutritional supplement called Impact — which contains specific nutrients thought to support the immune system — alongside standard immunotherapy (anti-PD-1 drugs) for people with advanced melanoma (skin cancer that has spread or cannot be removed). The goal is to see whether the supplement improves treatment outcomes.

You may be eligible if:
- You are 18 or older
- You have been confirmed by biopsy to have stage III (unresectable) or stage IV melanoma
- You are about to start treatment with an anti-PD-1 immunotherapy drug (alone or in combination)
- Your PD-L1 status has been assessed as part of standard care

You may NOT be eligible if:
- Your melanoma is at an earlier stage that can be surgically removed
- You have already received immunotherapy for your melanoma
- You have serious autoimmune disease or other conditions that make immunotherapy unsafe
- You are pregnant or breastfeeding

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (18)

- Age e 18 years;
- Histologically confirmed stage III (unresectable) or stage IV Cutaneous Melanoma;
- PD-L1 evaluation and as per standard clinical practice, patients with PD-L1 \< 1% will be treated with anti PD1 based regimen and patients with PD-L1\>1% will be treated with anti-PD1 in monotherapy;
- Anti-PD1 (Nivolumab) or anti PD1 based regimen (Nivolumab plus Ipilimumab or Nivolumab plus Relatlimab) planned as per standard clinical practice and decision by the treating oncologist; ;
- Measurable disease by computed tomography (CT) or Magnetic Resonance Imaging (MRI) per RECIST 1.1 criteria;

... and 13 more (see full listing online)

Exclusion (11)

- Active brain metastases;
- Patients with previous malignancies unless a complete remission was achieved at least 2 years prior to study entry;
- Patients with prior systemic anticancer therapy for unresectable or metastatic melanoma;
- Any serious or uncontrolled medical disorder or active infection that, in the opinion of the investigator, may increase the risk associated with study participation, study drug administration, or would impair the ability of the patient to receive protocol therapy;

• Presence of active, known, or suspected autoimmune disease;

... and 6 more (see full listing online)

Locations (1 total)

Istituto Nazionale Tumori IRCCS - Fondazione "G. Pascale", Napoli, Italy