

# Biomarkers in Immunotherapy of Melanoma

NCT05878977

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Institute of Oncology Ljubljana
Enrollment	150 participants

## Plain Language Summary

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This study collects blood and tissue samples from patients with advanced melanoma (skin cancer that has spread) who are starting their first immunotherapy treatment. The goal is to find biological markers that can predict which patients will respond best to immunotherapy drugs like nivolumab, ipilimumab, or pembrolizumab.

**\*\*You may be eligible if...\*\***

- You are over 18 with confirmed advanced melanoma (Stage IIID unresectable or Stage IV)
- You are about to start your first systemic immunotherapy treatment
- You had a full-body scan (CT or PET-CT) within 4 weeks before starting treatment
- You are in reasonably good health (ECOG 0–2)

**\*\*You may NOT be eligible if...\*\***

- You have already received systemic therapy for melanoma
- Your performance status is very poor (ECOG 3–4)
- You have known immune deficiency, are on immunosuppressants, or have active autoimmune disease
- You have another active cancer (except treated skin cancer)

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

## Key Eligibility Criteria

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### Inclusion (7)

- Age over 18 years
- Cytologically or histologically verified malignant melanoma
- Stage IIID unresectable/IV according to AJCC classification (8th edition, 2018)
- Performance status according to WHO 0 - 2 (ECOG criteria)
- 1st line of systemic treatment with immunotherapy (nivolumab, ipi/nivo, pembrolizumab)

... and 2 more (see full listing online)

### Exclusion (4)

- Previously treated melanoma with systemic therapy
- Capacity status according to WHO 3 - 4 (ECOG criteria)
- Contraindications for immunotherapy treatment (known deficiency of the immune system or active immunosuppressive treatment or active autoimmune disease requiring treatment)
- Other malignant diseases (except cured basal cell carcinoma and squamous cell carcinoma)

## Locations (1 total)

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Institute of Oncology Ljubljana, Ljubljana, Slovenia

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<https://clinicaltrials.gov/study/NCT05878977>

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