

Generation of an Artificial Intelligence Algorithm Based on the Analysis of Melanoma Peri-scar Dermatoheliosis, as a Predictive Factor of Response to Anti-PD-1

NCT05856565

Status	RECRUITING
Sponsor	Nantes University Hospital
Enrollment	700 participants

Plain Language Summary

This study is using artificial intelligence (AI) to analyze patterns in skin photos near melanoma scars (called dermatoheliosis — sun-damaged skin) to predict whether a patient's melanoma or skin cancer will respond to immunotherapy (anti-PD-1 drugs).

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

- You are an adult with inoperable stage III or IV melanoma, or inoperable squamous cell or basal cell skin carcinoma
- For the retrospective group: you have already received systemic (body-wide) treatment for at least 3 months with at least 6 months of follow-up
- For the prospective group: you are about to start immunotherapy for the first time for your melanoma
- You consent to participate and agree to having photos taken

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

- You received adjuvant immunotherapy within 6 months before starting curative treatment
- Your primary skin cancer site cannot be photographed (e.g., uveal or mucosal melanomas in inaccessible areas)

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

Key Eligibility Criteria

Inclusion (4)

- Adult patients with inoperable stage III or IV melanoma, or inoperable skin carcinoma (cutaneous squamous cell carcinoma or basal cell carcinoma)
- Retrospective cohort: patients who received systemic treatment for their inoperable skin cancer for at least 3 months, with at least 6 months of follow-up, without immunosuppression and whose site of the primary tumor is not altered by a concomitant dermatosis
- Prospective cohort: Patients naïve to immunotherapy for the management of their melanoma at the introduction of systemic treatment. Adjuvant immunotherapy tolerated if it has been stopped for at least 6 months before starting the curative treatment
- Patients who have expressed their agreement to participate in the research and who have signed an image rights authorization

Exclusion (9)

- Retrospective cohort: Patients who received their systemic skin cancer treatment for less than 90 days
- Patients who received adjuvant immunotherapy in the 6 months preceding the curative treatment
- Patients whose primary skin cancer site cannot be photographed (example of choroidal melanomas, mucosal melanomas except for melanomas with a vulvar or penile starting point, etc.)
- Patients treated with systemic corticosteroids (dose greater than 10 mg/day) at the introduction of the immunotherapy under consideration
- Immunocompromised patients (associated blood disease, human immunodeficiency virus infection, transplant patient, etc.)

... and 4 more (see full listing online)
<https://clinicaltrials.gov/study/NCT05856565>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

Locations (4 total)

Besancon University Hospital, Besançon, Bourgogne-Franche-Comté, France

Brest University Hospital, Brest, Finistère, France

Angers University Hospital, Angers, Maine-et-Loire, France

... and 1 more locations