Precision Radiation of Immune Checkpoint Therapy Resistant Melanoma Metastases

NCT04793737

Status	RECRUITING
Phase	Not Applicable
Sponsor	Karolinska University Hospital
Enrollment	27 participants

Plain Language Summary

This trial is for people with metastatic melanoma (skin cancer that has spread to other parts of the body) whose cancer has stopped responding to immunotherapy drugs that block PD-1 (such as pembrolizumab or nivolumab). The study is testing whether adding precise, targeted radiation to the areas of resistance can help restart the immune system's attack on the cancer.

You may be eligible if...
- You are 18 or older
- You have unresectable metastatic cutaneous (skin) melanoma
- You started PD-1 inhibitor immunotherapy as your first treatment
- You have been on immunotherapy for at least 3 months
- Your cancer has progressed or did not respond to immunotherapy
- Your overall health status is good (ECOG 0–1)

You may NOT be eligible if...
- You have not yet tried immunotherapy
- Your cancer is not melanoma
- Your health is not good enough to tolerate radiation therapy

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

Key Eligibility Criteria

Inclusion (7)

- Age 18 and above
- ECOG performance status of 0-1
- Signed and dated written informed consent before the start of specific protocol procedures.
- Patient has initiated PD-1 inhibitor treatment (alone or in combination with CTLA-4 inhibitor) as the first line of therapy for unresectable metastatic cutaneous melanoma and been on the treatment for at least 3 months and progressed on the treatment. Patients with primary or secondary resistance to the PD-1 inhibitor treatment will be included. Progression is defined as at least 30% enlargement of at least one metastasis or appearance of new metastasis. A fine-needle aspiration (FNA) biopsy from a progressing lesion or a new lesion is recommended to confirm the presence of viable tumor cells.
- Patients on adjuvant treatment with PD-1 inhibitors that during the treatment develop unresectable biopsy confirmed metastases can also be included in the study.

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

Exclusion (9)

- Inability to understand given information or undergo study procedures according to protocol
- Pregnant or breast-feeding. Patients must agree to use safe contraception during and for 3 months after study treatment.

https://clinicaltrials.gov/study/NCT04793737

• A condition requiring systemic treatment with either corticosteroids (\> 10 mg daily prednisone equivalents) or other immuno-suppressive medications within 30 days before start of study treatment. Inhaled or topical steroids and adrenal replacement doses \>10 mg daily prednisone equivalents are permitted.

• Has an active infection requiring systemic therapy.

• Concomitant therapy with any anti-tumor medications, other than PD-1/CTLA-4 inhibitors or 30 days before and after treatment in this trial.

... and 4 more (see full listing online)

Locations (1 total)

Division of Head-Neck, Lung and Skin cancers, Theme Cancer, Karolinska University Hospital, Stockholm, Sweden