Melanoma Margins Trial-II: 1cm v 2cm Wide Surgical Excision Margins for AJCC Stage II Primary Cutaneous Melanoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Patients may be included in the study if they meet ALL of the following criteria: 1. 1. Patients must have a Stage II primary invasive cutaneous melanoma (pT2b-pT4b, AJCC 8th edition) with Breslow thickness \>1.0mm to 2.0mm; \>2.0mm to 4.0mm or \>4.0mm with ulceration, or \>2.0mm to 4.0mm; or \>4.0mm without ulceration (Table 1) as determined by diagnostic biopsy (narrow excision, incision, shave or punch biopsy) and subsequent histopathological analysis. 2. Must have a primary melanoma that is cutaneous (including head, neck, trunk, extremity, scalp, palm or sole). 3. An uninterrupted 2cm margin must be technically feasible around biopsy scar or primary melanoma. 4. 4. Surgical intervention (which refers to the staging -SLNB and WLE as these are both to be done on the same day) must be completed within 120 days of the original diagnosis. Surgical intervention must also be performed within 28 days of randomisation. 5. Patients must be 18 years or older at time of consent. 6. Patient must be able to give informed consent and comply with the treatment protocol and follow up plan. 7. Life expectancy of at least 5 years from the time of diagnosis, not considering the melanoma in question, as determined by the PI. 8. Patients must have an ECOG performance score between 0 and 1 at screening. 9. A survivor of prior cancer is eligible provided that ALL of the following criteria are met and documented: * The patient has undergone potentially curative therapy for all prior malignancies, * There has been no evidence of recurrence of any prior malignancies for at least FIVE years (with the exception of successfully treated uterine/cervical or non-melanoma skin cancers (SCCs/BCCs) with no evidence of recurrence), and * The patient is deemed by their treating physician to be at low risk of recurrence from previous malignancies.

Exclusion Criteria:

Patients will be excluded from the study for ANY of the following reasons: 1. Uncertain diagnosis of melanoma i.e., so-called 'melanocytic lesion of unknown malignant potential'. 2. Patient has already undergone WLE at the site of the primary index lesion. 3. Patient unable or ineligible to undergo staging SLNB of the primary index lesion. 4. Perineural invasion or neurotropic melanoma: Neurotropism or perineural invasion in any type of melanoma is an exclusion. Perineural invasion does not include entrapment of nerves within the main primary tumour mass. 5. Desmoplastic melanoma: with any patient where pathology determines melanoma as PURE desmoplastic (as per WHO definition of \>90% desmoplasia), they are not eligible for this study. However melanomas with less than 90% desmoplasia or mixed desmoplastic subtypes are eligible unless there is neurotropism present (perineural invasion). 6. Microsatellitosis (a nest of metastatic tumour cells found to be growing away from the primary tumour) as per AJCC 8th edition definition is an exclusion. 7. Subungual melanoma 8. Patient has already undergone a local flap reconstruction of the defect after excision of the primary and determination of an accurate excision margin is impossible. 9. History of previous or concurrent (i.e. \>1 primary melanoma) invasive melanoma. 10. Melanoma located distal to the metacarpophalangeal joint; on the tip of the nose; the eyelids or on the ear; genitalia, perineum or anus; mucous membranes or internal viscera. 11. Physical, clinical, radiographic or pathologic evidence of satellite, in-transit, regional, or distant metastatic melanoma. 12. Patient has undergone surgery on a separate occasion to clear the lymph nodes of the probable draining lymphatic field, including -SLNB, of the index melanoma. 13. Any additional solid tumour or hematologic malignancy during the past 5 years (with exception of non- melanoma skin cancers (T1 skin lesions of squamous cell carcinoma (SCCs), basal cell carcinoma (BCCs)), or uterine/cervical cancer). 14. Melanoma-related operative procedures not corresponding to criteria described in the protocol. 15. Planned adjuvant radiotherapy to the primary melanoma site after wide local excision is not permitted as part of the protocol and any patients given this treatment would be excluded from the study. 16. History of organ transplantation. 17. Oral or parenteral immunosuppressive agents (not topical or inhaled steroids) at enrolment or within 6 months prior to enrolment. Pregnancy is not a specific exclusion criterion for this trial, though it may not be clinically appropriate to perform a wide excision and SLNB until the pregnancy has been completed, which may exclude the patient due to violation of inclusion criterion 4. We would advise careful counselling of the patient prior to enrolling the patient, which would include a discussion at the treating centre's multidisciplinary team meeting or tumour board. We would strongly advise contacting the central trial office to discuss the case prior to enrolling on the study.

Conditions & Interventions

Interventions:
PROCEDURE: Wide Local Excision = 1cm Margin, PROCEDURE: Wide Local Excision = 2cm Margin
Conditions:
Cutaneous Melanoma, Stage II
Keywords:
Malignant, Melanoma, Cancer, Surgery

More Information

Contact(s): Melanoma and Skin Cancer Trials Coordinator - melmart@masc.org.au
Principal Investigator:
Phase: NA
IRB
Number:
System ID: NCT03860883
