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1 cm vs 2 cm wide surgical excision margins for primary cutaneous melanoma

Submission date 02/06/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 06/07/2021	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 24/10/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-how-much-tissue-to-remove-during-surgery-for-melanoma-skin-cancer-melmart-ii

Background and study aims
Melanoma accounts for the great majority of skin cancer deaths in the UK. Since the 1990s the diagnosis of melanoma has more than doubled. According to World Health Organisation statistics, the UK has one of the highest death rates from skin cancer in the world. In contrast to most other cancers, melanoma tends to affect much younger people, with nearly half the patients diagnosed at under 65 years old.
Melanoma has a tendency for recurring around the original biopsy (tissue sample) site in a very aggressive manner, making it a very challenging problem to treat when it occurs. To prevent local recurrence, the standard treatment has been to take a further safety margin of normal skin and soft tissue around the original melanoma biopsy site. This treatment is offered to every patient diagnosed with melanoma. Surprisingly, this margin of safety has yet to be standardised for melanoma, with a significant variety of excision margins being recommended in different countries (from 1 cm to 3 cm depending on the initial stage of the disease). Since melanoma commonly occurs in the head and neck region or on the limbs, the cosmetic and functional implications for patients with such large defects are substantial.
The rate of local recurrence for melanoma is quite low (2-8%) and, despite several large clinical trials, there is little evidence that performing such wide excisions changes recurrence rates or improves survival for our patients. Given that the overall 10-year survival for melanoma is now 90% internationally, with about 150,000 people in the UK currently living with the diagnosis, this has become a key survivorship issue for these patients.
The aim of this study is to find out whether a 1 cm excision margin is as safe as a 2 cm margin for high-risk melanoma of the skin. This study is designed to show that the risk of long-term pain associated with surgery can be halved and quality of life can be improved with a 1 cm margin due to reduced side effects and need for reconstructive surgery after treatment. This study will also evaluate the economic impact of safely using less surgery for the NHS and society in general.

Who can participate?
Patients aged 18 and over with primary invasive cutaneous melanoma

What does the study involve?
Patients are randomly allocated to be treated with a 1 cm or 2 cm wide local excision margin. During the first 2 years after surgery patients should attend follow up at 3, 6, 12, 18 and 24 months (+/- 2 weeks) preferably in clinic, but telehealth consultations are permitted. For years 3 to 5 patients attend annual follow up visits. For years 6 to 10 patients attend annual follow-up visits. These visits are optional and are based on local standard practice or clinician decision. If the patient cannot be contacted, survival data will be collected.

What are the possible benefits and risks of participating?
The intervention is a small change to the standard treatment so there are no significant risks from taking part, over and above the risks of surgery which the treating clinician would ordinarily discuss with the patient as part of the standard consent process. Similarly, there are no direct benefits to the patient from participating in this study.

Where is the study run from?
Melanoma and Skin Cancer Trials Ltd (Australia)

When is the study starting and how long is it expected to run for?
February 2009 to December 2029

Who is funding the study?
1. National Health and Medical Research Council (Australia)
2. National Institute for Health and Care Research (UK)

Who is the main contact?
1. Miss Tiiu Sildva, melmart2@nds.ox.ac.uk
2. Mrs Jo Cook, melmart2@nds.ox.ac.uk

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
257226

ClinicalTrials.gov (NCT)
NCT03860883

Protocol serial number
IRAS 257226, HTA - NIHR130886

Study information

Scientific Title
Melanoma Margins Trial-II (MelMarT-II): 1 cm vs 2 cm wide surgical excision margins for AJCC stage II primary cutaneous melanoma

Acronym
MelMarT-II

Study objectives
Patients with a primary invasive melanoma are recommended to undergo excision of the primary lesion with a wide margin. There is evidence that less radical margins of excision may be just as safe. This is a randomised controlled trial of 1 cm versus 2 cm margin of excision of the primary lesion for adult patients with stage II primary invasive cutaneous melanomas (American Joint Committee on Cancer [AJCC] 8th edition) to determine differences in disease-free survival. A reduction in margins is expected to improve patient quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2021, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, NG1 6FS, UK; +44 (0)207 104 8102, +44 (0)207 104 8102, +44 (0) 207 104 8134; CambridgeEast.REC@hra.nhs.uk), REC ref: 19/EE/0369

Study design
Phase III multi-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cutaneous melanoma

Interventions
A wide local excision involves removing an extra "safety margin" of skin surrounding the original melanoma site, to ensure that any remaining scattered melanoma tumour cells that may have been left behind after the first initial biopsy/surgery are removed.

Patients will be randomised 1:1 using a randomisation system to one of two study arms:

Experimental: arm A
1 cm wide local excision margin + sentinel lymph node biopsy +/- reconstruction

Active comparator: arm B
2 cm wide local excision margin + sentinel lymph node biopsy +/- reconstruction

Years 1 to 2: During the first 2 years patients should attend follow up at 3, 6, 12, 18 and 24 months (+/- 2 weeks) after surgery preferably in clinic, however telehealth consultations are permitted

Years 3 to 5: Annual follow up study visits should be performed (+/- 4 weeks) preferably in clinic, however telehealth consultations are permitted.

Years 6 to 10: Annual follow up study visits should be performed (+/- 4 weeks). These visits are optional and are based on local standard practice or clinician decision. The annual follow up visits in years 6-10 can be performed via the patient’s regular scheduled study visit or via telehealth consultations with the patient or their treating clinician. If the patient cannot be contacted, survival data will be collected.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 30/04/2025:
Disease-free survival (DFS): time from randomisation until the first clinically, histologically or radiologically confirmed recurrence of melanoma at any body site, or death from any cause

Previous primary outcome measure:
Disease-free survival: time from randomisation to any clinically, histologically or radiologically confirmed local recurrence of melanoma including satellite lesions and in transit metastases to regional draining lymph nodes (time frame: 0-60 months)

Key secondary outcome(s))

Current secondary outcome measure as of 30/04/2025:
1. Local recurrence free survival (LRFS): Time from randomisation to any clinically, histologically or radiologically confirmed LR of melanoma, including satellite lesions and in transit metastases between the primary site and the regional draining lymph nodes or death from any cause.
2. Distant disease-free survival (DDFS): Time from randomisation to any clinically, histologically or radiologically confirmed distant recurrence of melanoma or death from any cause.
3. Melanoma-specific survival (MSS): Time from randomisation to death due to melanoma.
4. Overall survival (OS): Time from randomisation to death from any cause.
5. QoL and neuropathic pain assessments at baseline, 3, 6, 12 and 24 and at melanoma recurrence.
6. Surgery-related adverse events up to 12 months from the date of surgery.
7. Serious Adverse Events within 1 year.
8. Health economic evaluation, resource utilisation and cost-utility analysis.

Previous secondary outcome measure:
1. Local recurrence: time from randomisation to any clinically, histologically or radiologically confirmed local recurrence of melanoma including satellite lesions and in transit metastases to regional draining lymph nodes (time frame: day 0 - trial completion (max. 120 months))
2. Distant disease-free survival: time from randomisation to any clinically, histologically or radiologically confirmed distant recurrence of melanoma (time frame: day 0 - trial completion (max. 120 months))
3. Melanoma-specific survival: time from randomisation to death due to melanoma (time frame: day 0 - trial completion (max. 120 months))
4. Overall survival: time from randomisation to death from any cause (time frame: day 0 - trial completion (max. 120 months))
5. Melanoma-specific quality of life measured using the Functional Assessment of Cancer Therapy - Melanoma (FACT-M) questionnaire at baseline, 3, 6, 12 and 24 months
6. Neuropathic pain assessed using PainDetect questionnaire at baseline, 3, 6, 12 and 24 months
7. Health-related quality of life measured using the EQ-5D-5L questionnaire at baseline, 3, 6, 12 and 24 months
8. Surgery-related adverse events (wound dehiscence, seroma/haematoma, haemorrhage, infection, skin graft failure, necrosis of flap used for reconstruction, deep venous thrombosis, urinary tract infection, pneumonia, cardiac complications, lymphedema), graded in severity according to the Clavien-Dindo system, recorded from the time of surgery to 90 days following surgery (inclusive)
9. Adverse events (AEs): for the purposes of this trial, only those pre-existing conditions and AEs related to the patient's melanoma diagnosis and/or with study treatment (wide local excision surgery, including sentinel lymph node biopsy) will be reported. AEs and any pre-existing medical conditions will be recorded at the baseline assessment and routinely until 12 months of follow up, or until the participant withdraws or dies (prior to completing 12 months of follow up).
10. Health economic evaluation: resource utilisation and cost-utility analysis from hospital notes, Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data (Australia) and patient-reported outcomes (including an employment questionnaire), at baseline, 3, 6, 12, and 24 months and at melanoma recurrence

Completion date

31/12/2029

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 25/04/2025:
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. 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:
9.1. The patient has undergone potentially curative therapy for all prior malignancies,
9.2. 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
9.3. The patient is deemed by their treating physician to be at low risk of recurrence from previous malignancies.

Previous participant inclusion criteria:
1. Patients must have a stage II primary invasive cutaneous melanoma with Breslow thickness >2 mm without ulceration, or >1 mm (with ulceration only) (pT2b-pT4b, AJCC 8th edition) as determined by diagnostic biopsy (narrow excision, incision 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 2 cm margin must be technically feasible around biopsy scar or primary melanoma
4. Staging sentinel node biopsy must be completed within 3 months (92 days) of the original diagnosis
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 principal investigator (PI)
8. Patients must have an Eastern Cooperative Oncology Group (ECOG) performance score between 0 and 1
9. A survivor of prior cancer is eligible provided that ALL of the following criteria are met and documented:
9.1. The patient has undergone potentially curative therapy for all prior malignancies
9.2. There has been no evidence of recurrence of any prior malignancies for at least FIVE years

(except for successfully treated cervical or non-melanoma skin cancer with no evidence of recurrence), and
9.3. The patient is deemed by their treating physician to be at low risk of recurrence from previous malignancies

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current participant exclusion criteria as of 25/04/2025:
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.

Please note:
1. 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.
2. We would advise careful counselling of the patient prior to enrolment, which would include a discussion at the treating centre’s multidisciplinary team meeting or tumour board and the central trial office.

Previous participant exclusion criteria:
1. Uncertain diagnosis of melanoma i.e. so-called 'melanocytic lesion of unknown malignant potential'
2. Patient has already undergone wide local excision at the site of the primary index lesion
3. Patient unable or ineligible to undergo staging sentinel lymph node biopsy of the primary index lesion
4. Desmoplastic or neurotropic melanoma
5. Microsatellitosis as per AJCC 8th edition definition
6. Subungual melanoma
7. 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
8. History of previous or concurrent (i.e., second primary) invasive melanoma
9. 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
10. Physical, clinical, radiographic or pathologic evidence of satellite, in-transit, regional, or distant metastatic melanoma
11. Patient has undergone surgery on a separate occasion to clear the lymph nodes of the probable draining lymphatic field, including sentinel lymph node biopsy, of the index melanoma
12. Any additional solid tumour or hematologic malignancy during the past 5 years except T1 skin lesions of squamous cell carcinoma, basal cell carcinoma, or uterine/cervical cancer
13. Melanoma-related operative procedures not corresponding to criteria described in the protocol
14. 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
15. History of organ transplantation
16. 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 sentinel node biopsy until the pregnancy has been completed, which is likely to exclude the patient due to violation of inclusion criterion 4. The researchers 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. They would strongly advise contacting the central trial office to discuss the case prior to enrolling on the study.

Date of first enrolment

09/01/2020

Date of final enrolment
28/08/2025

Locations

Countries of recruitment
United Kingdom

England

Wales

Australia

Canada

New Zealand

Sweden

United States of America

Study participating centre
Norfolk & Norwich University Hospital
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Study participating centre
Peter MacCallum Cancer Centre
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Study participating centre
Alfred Hospital
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Study participating centre
Melanoma Institute Australia
The Poche Centre, 40 Rocklands Rd
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Study participating centre
Royal Prince Alfred Hospital
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2050

Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Melanoma and Skin Cancer Trials Ltd

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
National Health and Medical Research Council

Alternative Name(s)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Marc Moncrieff (marc.moncrieff@nnuh.nhs.uk) and MASC (melmart@masc.org.au).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version V4.0	06/05/2021	06/07/2021	No	Yes
Participant information sheet	version 7.0	07/02/2022	07/11/2023	No	Yes
Participant information sheet	Including informed consent form version 10.0	26/02/2025	25/04/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	02/01/2024	18/08/2024	No	No
Protocol file	version 4.0	08/11/2024	30/04/2025	No	No
Protocol file	UK Appendix version 10.0	26/02/2025	30/04/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes