

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

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<b>Registration date</b> 06/07/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/03/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

## Contact information

### Type(s)

Public

### Contact name

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### Contact details

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### Type(s)

Scientific

### Contact name

Mrs Jo Cook

### Contact details

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-  
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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**

Mixed

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

All

**Total final enrolment**

3008

**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**

Colney Ln

Norwich

England

NR4 7UY

**Study participating centre**

**St Thomas' Hospital**

Westminster Bridge Road

London

England

SE1 7EH

**Study participating centre**

**Hull Royal Infirmary**

Anlaby Road  
Hull  
England  
HU3 2JZ

**Study participating centre**

**Cambridge University Hospitals**

Cambridge Biomedical Campus  
Hills Road  
Cambridge  
England  
CB2 0QQ

**Study participating centre**

**St Mary's Hospital**

The Bays  
South Wharf Road  
London  
England  
W2 1BL

**Study participating centre**

**James Cook University Hospital**

Marlon Road  
Middlesbrough  
England  
TS4 3BW

**Study participating centre**

**Mid-Essex Hospitals**

Prittlewell Chase  
Westcliff-On-Sea  
England  
SS0 0RY

**Study participating centre**

**Southmead Hospital**

Southmead Road  
Westbury-On-Trym  
Bristol

England  
BS10 5NB

**Study participating centre**  
**Nottingham University Hospital**  
Queens Medical Centre  
Derby Road  
Nottingham  
England  
NG7 2UH

**Study participating centre**  
**John Radcliffe Hospital**  
Headley Way  
Headington  
Oxford  
England  
OX3 9DU

**Study participating centre**  
**Royal Free Hospital**  
Pond Street  
London  
England  
NW3 2QG

**Study participating centre**  
**St George's Hospital**  
Blackshaw Road  
London  
England  
SW17 0QT

**Study participating centre**  
**Whiston Hospital**  
Warrington Road  
Prescot  
England  
L35 5DR

**Study participating centre**

**The Christie**

550 Wilmslow Road

Withington

Manchester

England

M20 4BX

**Study participating centre**

**St. James's University Hospital**

Beckett Street

Leeds

England

LS9 7TF

**Study participating centre**

**The Royal Marsden Hospital**

Fulham Road

London

England

SW3 6JJ

**Study participating centre**

**Queen Elizabeth Hospital**

Mindelsohn Way

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England

B15 2GW

**Study participating centre**

**Royal Preston Hospital**

Sharoe Green Lane

Fulwood

Preston

England

PR2 9HT

**Study participating centre**

**Royal Cornwall Hospital (treliste)**

Treliske

Truro  
England  
TR1 3LJ

**Study participating centre**  
**Royal Victoria Infirmary**  
Newcastle University Hospitals NHS Foundation Trust  
Plastics Research  
Research Office, Room 12  
Peacock Hall  
Newcastle upon Tyne  
England  
NE1 4LP

**Study participating centre**  
**Peter MacCallum Cancer Centre**  
305 Grattan Street  
Melbourne  
Australia  
3000

**Study participating centre**  
**Alfred Hospital**  
55 Commercial Road  
Melbourne  
Australia  
3004

**Study participating centre**  
**Melanoma Institute Australia**  
The Poche Centre, 40 Rocklands Rd  
Wollstonecraft  
Australia  
2065

**Study participating centre**  
**Royal Prince Alfred Hospital**  
50 Missenden Rd  
Camperdown  
Australia  
2050

**Study participating centre**  
**Sahlgrenska University Hospital**  
Bla Straket 5  
Goteborg  
Sweden  
413 45

**Study participating centre**  
**Rutgers Cancer Institute of New Jersey**  
195 Little Albany St  
New Jersey  
United States of America  
08901

**Study participating centre**  
**The Angeles (Cedars-Sinai Medical Center and its Affiliates)**  
11818 Wilshire Blvd  
Los Angeles  
United States of America  
90025

**Study participating centre**  
**Memorial Sloan Kettering Cancer Center**  
1275 York Ave  
New York  
United States of America  
10065

**Study participating centre**  
**Huntsman Cancer Institute (University of Utah)**  
2000 Cir of Hope Dr  
Salt Lake City  
United States of America  
84112

**Study participating centre**  
**Emory University**  
201 Dowman Dr

Atlanta  
United States of America  
30322

**Study participating centre**  
**Calvary Public Hospital Bruce**  
5 Mary Potter Ct  
Bruce  
Australia  
2617

**Study participating centre**  
**North Shore Hospital**  
124 Shakespeare Rd  
Auckland  
New Zealand  
0620

**Study participating centre**  
**Sunnybrook Health Sciences Centre**  
2075 Bayview Ave  
Toronto  
Canada  
M4N 3M5

**Study participating centre**  
**Fox Chase Cancer Center**  
333 Cottmann Ave  
Philadelphia  
United States of America  
19111

**Study participating centre**  
**Hopital Maisonneuve-Rosemont**  
5415 Assumption Blvd  
Montreal  
Canada  
H1T 2M4

**Study participating centre****Hotel-Dieu de Quebec**

11 Cote du Palais  
Quebec City  
Canada  
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**Study participating centre****Royal Victoria Regional Health Centre**

201 Georgian Dr  
Barrie  
Canada  
L4M 6M2

**Study participating centre****Juravinski Cancer Centre - Hamilton Health Sciences**

669 Concession St  
Hamilton  
Canada  
L8V 5C2

**Study participating centre****Central Hospital Kristianstad**

J A Hedlunds vag 5  
Kristianstad  
Sweden  
29133

**Study participating centre****Ottawa Hospital Research Institute**

1053 Carling Ave  
Ottawa  
Canada  
K1Y 4E9

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version V4.0	06/05/2021	06/07/2021	No	Yes
<a href="#">Participant information sheet</a>	version 7.0	07/02/2022	07/11/2023	No	Yes
<a href="#">Participant information sheet</a>	Including informed consent form version 10.0	26/02/2025	25/04/2025	No	Yes
<a href="#">Protocol file</a>	version 3.0	02/01/2024	18/08/2024	No	No
<a href="#">Protocol file</a>	version 4.0	08/11/2024	30/04/2025	No	No
<a href="#">Protocol file</a>	UK Appendix version 10.0	26/02/2025	30/04/2025	No	No
<a href="#">Protocol file</a>	version 5.0	12/12/2025	26/03/2026	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes