# Randomised trial of width of surgical excision of thick cutaneous malignant melanoma

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
19/08/2002	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	Results
Last Edited	Condition category	[] Individual participant data
10/03/2015	Cancer	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

Type(s)

Scientific

Contact name

- -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

#### Additional identifiers

Protocol serial number ICR/MELANOMA

# Study information

#### Scientific Title

Randomised trial of width of surgical excision of thick cutaneous malignant melanoma

#### **Study objectives**

This national randomised prospective trial is designed to establish the optimal surgical margins of excision of melanomas with a Breslow thickness 2 mm or larger. It compares recurrence and survival in two groups of patients: those whose melanomas were excised with a 1 cm margin of normal skin (requiring only out-patient surgery) or with a 3 cm margin (usually requiring inpatient surgery, skin grafting and admission for up to one week). The quality of life in the two groups will be assessed after surgery and during follow up. The feasibility of this trial has been demonstrated by the success of the pilot phase in which 170 patients have been entered from 41 participating centres.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Malignant melanoma

#### **Interventions**

Two surgical options are available:

#### A. PROPOSED STUDY:

The primary melanoma is locally excised with a 1 mm margin of macroscopically normal skin. Within 45 days of initial surgery patients are randomised to:

- 1. Group A: Surgery, re-excision with a 1 cm margin.
- 2. Group B: Surgery, re-excision with a 3 cm margin.

#### **B. ALTERNATIVE STUDY:**

The primary melanoma is locally excised (wide excision) with a 1 cm margin of macroscopically normal skin. Within 45 days of initial surgery patients are randomised to:

- 1. Group C: Surgery, re-excision with a further 2 cm margin.
- 2. Group D: No further treatment.

#### Intervention Type

Procedure/Surgery

#### Primary outcome(s)

Quality of life

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

31/05/2001

## Eligibility

#### Key inclusion criteria

- 1. Aged over 18 years
- 2. Single primary localised melanoma of depth 2 mm or greater
- 3. Melanoma must not be located on head, neck, fingers, toes, soles of feet or palms of hands (patients with melanomas on dorsum of hands and feet are eligible)
- 4. No prior history of other malignancies, except basal cell carcinoma
- 5. Not receiving immunosuppressive therapy

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

30/04/1998

#### Date of final enrolment

31/05/2001

#### Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre MRC Clinical Trials Unit

London

# Sponsor information

#### Organisation

UK Co-ordinating Committee for Cancer Research (UKCCCR)

#### **ROR**

https://ror.org/054225q67

# Funder(s)

#### Funder type

Not defined

#### **Funder Name**

Not provided at time of registration

### **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration