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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
- - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 in-patient 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Quality of life

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/04/1998

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details
MRC Clinical Trials Unit
222 Euston Road
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Sponsor type
Government

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration