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Sentinel lymph node biopsy feasibility study in patients with primary cutaneous melanoma

Submission date 01/10/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 10/01/2005	**Overall study status** Completed	
Last Edited 26/04/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-to-investigate-the-diagnosis-and-treatment-of-melanoma-skin-cancer-with-sentinel-lymph-node-biopsy

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Sentinel lymph node biopsy feasibility study in patients with primary cutaneous melanoma

Acronym
SLNB

Study objectives
To compare the overall and disease-free survival in patients with a positive lymph node at biopsy.

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
Melanoma

Interventions
Completion lymphadenectomy versus no surgery

Intervention Type
Other

Phase
Phase II/III

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
13/10/2006

Eligibility

Key inclusion criteria
1. Patients must have clinical stage I or II invasive cutaneous melanoma with Breslow thickness greater than 1.0 mm and be suitable for lymphadenectomy surgery
2. The primary site must be on the trunk, limbs or digits. Patients with a primary melanoma involving the ear, eye or mucous membranes are not eligible.
3. Primary excision must have been within 90 days prior to the initial clinic visit

4. Subjects must be at least 18 years old
5. Karnovsky performance status greater than 70%
6. Women of childbearing age must have a negative pregnancy test
7. Subjects must voluntarily sign an informed consent form before study entry and agree to complete follow-up assessments
8. Adequate bone marrow, renal and hepatic function

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Wide local excision of the primary tumour with greater than 1 cm excision margins before SLNB. Patients may have SLNB and still be eligible for excision margin studies after SLNB.
2. Clinical evidence of satellite, in-transit, regional nodal or distant metastases
3. A second primary invasive melanoma
4. Any malignancy in the past 5 years, except squamous cell carcinoma of the skin, basal cell carcinoma, in situ carcinoma of the uterine cervix, or Stage I laryngeal carcinoma
5. Prior surgery in the region of the primary draining nodal basin that would disrupt normal lymphatic drainage patterns
6. Previous chemotherapy, immunotherapy or radiation therapy
7. Pregnancy or breast feeding
8. Known hypersensitivity to 99mTc-nanocolloid or patent blue dye.
9. History of any severe medical condition that is a significant risk to the participant leading to a life expectancy of less than 10 years prior to diagnosis of melanoma

Date of first enrolment
01/09/2002

Date of final enrolment
13/10/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Marsden Hospital
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Sponsor not defined - Record supplied by Institute of Cancer Research

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes