ISRCTN80602070 https://doi.org/10.1186/ISRCTN80602070

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
Registration date 10/01/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/04/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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

Study website
http://www.icr.ac.uk/research/research_sections/clinical_trials/trials/2381_disease.shtml#

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Completion lymphadenectomy versus no surgery

Intervention Type
Other

Phase
Phase II/III

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

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
England

United Kingdom

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

Sponsor information

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

Sponsor details
Institute of Cancer Research
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Not defined

Funder(s)

Funder type

Charity

Funder Name
Cancer Research UK (CRUK) (UK)

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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