ISRCTN72807124 https://doi.org/10.1186/ISRCTN72807124

A phase III randomised, double-blind trial of immunotherapy with a polyvalent melanoma vaccine (C-VAX) plus bacille Calmette-Guerin (BCG) versus placebo plus BCG as a post surgical treatment for stage IV melanoma

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 05/03/2019	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0436044028

Study information

Scientific Title
A phase III randomised, double-blind trial of immunotherapy with a polyvalent melanoma vaccine (C-VAX) plus bacille Calmette-Guerin (BCG) versus placebo plus BCG as a post surgical treatment for stage IV melanoma

Study objectives
To establish whether adjuvant C-VAX plus BCG will prolong disease free and overall survival compared to placebo plus BCG in stage IV melanoma patients who have no evidence of disease post-surgery.

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)
Prevention

Health condition(s) or problem(s) studied
Stage IV melanoma

Interventions
Randomised controlled trial.

Intervention Type
Biological/Vaccine

Phase
Phase III

Drug/device/biological/vaccine name(s)
C-VAX, BCG

Primary outcome(s)
Progression free survival.

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

Completion date
01/08/2003

Eligibility

Key inclusion criteria
Patients with resected stage IV melanoma.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/04/1999

Date of final enrolment
01/08/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James's University Hospital
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration