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

Contact name
Dr PM Patel

Contact details
Medical Oncology
Cancer Studies
ICRF Research Building
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Progression free survival.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1999

Completion date
01/08/2003

Eligibility

Key inclusion criteria
Patients with resected stage IV melanoma.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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

England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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