

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

Primary study design

Interventional

Study design

Randomised controlled trial

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