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CarVin versus CarEto - A randomised phase II study of carboplatin and vinorelbine versus carboplatin and etoposide in good performance status small cell lung cancer patients presenting with adverse prognostic factors

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 04/07/2011	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0067120650

Study information

Scientific Title

Study objectives
A randomised phase II study of carboplatin and vinorelbine versus carboplatin and etoposide in good performance status small cell lung cancer patients presenting with adverse prognostic factors.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cancer: Small cell lung cancer

Interventions
1. Chemotherapy with carboplatin and vinorelbine
2. Chemotherapy with carboplatin and etoposide

Added July 2008: trial stopped because of poor recruitment

Intervention Type
Other

Phase
Phase II

Primary outcome measure
1. Toxicity
2. Tumour response

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/04/2002

Completion date
08/04/2006

Reason abandoned (if study stopped)
Insufficient personel

Eligibility

Key inclusion criteria
1. Elderly patients >65 years with good prognosis and Eastern Cooperative Oncology Group (ECOG) p/s <2
2. Confirmed small cell lung cancer not considered eligible for aggressive multimodality therapy

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
Total target recruitment = 80 patients

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/04/2002

Date of final enrolment
08/04/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clatterbridge Centre for Oncology
Wirral
United Kingdom
CH63 4JY

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
Government

Funder Name
Clatterbridge Centre for Oncology 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