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Medical Research Council Sixth Small Cell Study: A Controlled Clinical Trial of Two Policies of Chemotherapy for Poor Prognosis Patients with Small-Cell Lung Cancer (SCLC)

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 15/11/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
LU12

Study information

Scientific Title

Medical Research Council Sixth Small Cell Study: A Controlled Clinical Trial of Two Policies of Chemotherapy for Poor Prognosis Patients with Small-Cell Lung Cancer (SCLC)

Study objectives
(Added 05/08/09) What is the comparison in poor prognosis patients with SCLC with the standard chemotherapy used in 3 previous MRC studies, etoposide, cyclophosphamide, methotrexate and vincristine (ECMV) and 3 courses of etoposide & vincristine (EV), with respect to palliation of symptoms, performance status, toxicity, response to treatment and survival?

As of 05/08/09 this record has been extensively updated. All updates can be found under the relavent field with the above update date. Please also note that the trial start and end dates have been changed from 19/08/2002 and 19/08/2003 respectively, as these dates were automatically generated by the system at time of registration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics information required at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lung (small cell) cancer

Interventions
1. ECMV Regimen: Three courses three weeks apart of Etoposide, Cyclophosphamide, Methotrexate and Vincristine.
2. EV Regimen: Three courses three weeks apart of Etoposide and Vincristine. Thoracic radiotherapy and prophylactic cranial irradiation should not be given as a routine. If a patient needs radiotherapy to metastatic sites or to the primary site to control symptoms, the details should be decided by the radiotherapist and recorded as appropriate.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Etoposide, cylophosphamide, mathotrexate, vincristine

Primary outcome(s)

Added 05/08/09:
1. Palliation of symptoms
2. Toxicity
3. Performance status
4. Quality of life
5. Response rate

Initial outcome measures not provided at time of registration

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

Completion date
31/03/1999

Eligibility

Key inclusion criteria
1. Primarily untreated microscopically confirmed SCLC
2. Age <80
3. Limited disease: poor performance status (World Health Organisation [WHO] grade 3 or 4). Extensive disease: performance status any grade
4. Renal function normal
5. Plasma Billirubin not greater than twice normal levels

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Previous anticancer treatment for current SCLC
2. Presence of other malignant disease (except previous basal cell carcinoma or in situ carcinoma of the cervix)
3. Presence of other serious condition contraindicating the study regimens

Date of first enrolment
01/04/1997

Date of final enrolment
31/03/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Reseach Council (MRC) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/1996	15/11/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes