

# 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)

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/11/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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**  
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 relevant 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, cyclophosphamide, methotrexate, 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 Research 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?
<a href="#">Results article</a>	results	01/02/1996	15/11/2019	Yes	No