

# Randomised trial of two schedules of chemotherapy of the same dose/time intensity in untreated small cell lung cancer (SCLC) of poor prognosis

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/02/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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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United Kingdom  
NW1 2DA

## Additional identifiers

**Protocol serial number**  
TR7SCLC

## Study information

**Scientific Title**

Randomised trial of two schedules of chemotherapy of the same dose/time intensity in untreated small cell lung cancer (SCLC) of poor prognosis

**Study objectives**

Not provided at time of registration

**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

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Lung (small cell) cancer

**Interventions**

1. Standard Regimen:

Multi-drug chemotherapy, cyclophosphamide, adriamycin and vincristine alternating every 21 days with etoposide and cisplatin. A total of six courses, three with each drug combination.

2. Low Dose/High Frequency Regimen:

Multi-drug chemotherapy, etoposide and cisplatin alternating every 10/11 days with cyclophosphamide, adriamycin and vincristine. A total of twelve courses, six with each drug combination. This schedule uses the same drugs as in the standard regimen but at half the dose and twice the frequency with the same intended overall dose intensity.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Cyclophosphamide, adriamycin, vincristine, etoposide, cisplatin

**Primary outcome(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/12/2005

## Eligibility

### Key inclusion criteria

1. Histologically or cytologically proven small cell carcinoma of the lung
2. Aged 75 or under
3. Extensive disease and poor prognosis, ie Eastern Cooperative Oncology Group (ECOG) performance status 2 or 3 and/or alkaline phosphatase >1.5 upper limit of normal range
4. Adequate renal function
5. No previous malignancy, except non melanomatous skin cancer in the preceding 3 years
6. No previous chemotherapy or radiotherapy, except for emergency radiotherapy for superior vena cava obstruction
7. No medical contraindications to treatment

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Key exclusion criteria

Not provided at time of registration

### Date of first enrolment

01/01/2000

### Date of final enrolment

31/12/2005

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

# Sponsor information

## Organisation

UK Co-ordinating Committee for Cancer Research (UKCCCR)

## ROR

<https://ror.org/054225q67>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Cancer organisations

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration