

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

Submission date 01/07/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/02/2015	Condition category 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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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

Primary study design

Interventional

Study design

Randomised controlled trial

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