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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 24/02/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
- - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

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

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details
MRC Clinical Trials Unit
222 Euston Road
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United Kingdom
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Sponsor type
Government

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Research organisation

Funder Name

Cancer organisations

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