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	Recruitment status	Prospectively registered
01/07/2001	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
01/07/2001	Completed	Results
Last Edited	Condition category	Individual participant data
24/02/2015	Cancer	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

- - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Kev 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 London United Kingdom NW1 2DA

Sponsor type

Government

ROR

https://ror.org/054225q67

Funder(s)

Funder type

Research organisation

Funder Name

Cancer organisations

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration