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Weekly intensive versus standard chemotherapy in untreated small cell lung cancer (SCLC) patients with good 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 15/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TR6SCLC

Study information

Scientific Title
Weekly intensive versus standard chemotherapy in untreated small cell lung cancer (SCLC) patients with good 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

Health condition(s) or problem(s) studied
Lung (small cell) cancer

Interventions
1. Intensive Regimen: Chemotherapy, cisplatin and etoposide alternating every 7 days with ifosfamide and adriamycin. A total of twelve courses, six with each drug combination.
2. Standard Regimen: Chemotherapy, cisplatin and etoposide alternating every 21 days with ifosfamide and adriamycin. A total of six courses, three with each drug combination.

All limited disease patients who show complete or partial response following chemotherapy receive thoracic irradiation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cisplatin, etoposide, ifosfamide, adriamycin

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1988

Completion date
31/12/1992

Eligibility

Key inclusion criteria
1. Histologically or cytologically proven SCLC
2. Age 75 or under
3. Either limited disease or extensive disease in the good prognostic category. That is have both of the following characteristics, Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1 and alkaline phosphatase <1.5 upper limit of normal range
4. Adequate renal function
5. No previous malignancy, except non-melanomatous skin cancer
6. No previous chemotherapy or radiotherapy
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
01/01/1988

Date of final enrolment
31/12/1992

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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