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A randomised study of timing of thoracic irradiation in small cell lung cancer

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	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/10/2021	Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003364

Secondary identifying numbers
TR8SCLC

Study information

Scientific Title
A randomised study of timing of thoracic irradiation in small cell lung cancer

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
All patients receive chemotherapy, CAV (cyclophosphamide, Adriamycin, vincristine) followed by EC (etoposide, cisplatin). This sequence is repeated three times. Each course is given at 3 week intervals.

Patients are randomised to receive loco-regional irradiation as follows:
1. Early Radiotherapy Group: Loco-regional radiotherapy, 40 Gy given in fifteen fractions over 3 weeks with septrin prophylaxis. Radiotherapy to be given simultaneously with the first course of EC chemotherapy.
2. Late Radiotherapy Group: Loco-regional radiotherapy, 40 Gy given in fifteen fractions over 3 weeks with septrin prophylaxis. Radiotherapy to be given simultaneously with the third course of EC chemotherapy. If there is no evidence of progression following chemotherapy patients receive prophylactic brain irradiation (PCI), 25 Gy in ten fraction over 2 weeks.

Intervention Type
Drug

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1989

Completion date
31/01/2002

Eligibility

Key inclusion criteria
1. Histological or cytological proven small cell anaplastic carcinoma of the lung
2. Limited disease, that is, disease within the hemithorax, mediastinum or ipsilateral supraclavicular nodes
3. Measurable or evaluable disease
4. Fit to receive treatment
5. Aged <75 years
6. Life expectancy of more than 8 weeks
7. Eastern Cooperative Oncology Group (ECOG) performance status 0-3
8. No prior treatment with radiotherapy or chemotherapy
9. No history of prior malignancy, unless the patient has been without evidence of disease for at least 3 years or the tumour was a non melanoma skin tumour

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Patients with pleural effusions are not eligible
2. Patients with evidence of extensive disease are not eligible

Date of first enrolment

01/01/1989

Date of final enrolment
31/01/2002

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
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WC2A 3PX
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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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	6 results	20/08/2006	25/01/2019	Yes	No
Plain English results			28/10/2021	No	Yes