

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

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/10/2021	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00003364

Protocol serial number
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

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

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

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