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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
01/07/2001		☐ 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

Dr - -

#### 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

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

# 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 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, Cancer Research UK (CRUK), 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

# **Study outputs**

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