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Mitomycin, ifosfamide and cisplatin in non-small cell lung cancer (NSCLC): A randomised trial of chemotherapy plus radiotherapy versus radiotherapy alone

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 01/02/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003240

Secondary identifying numbers
LU3001

Study information

Scientific Title

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)
Not specified

Study type(s)
Not Specified

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 (non-small cell) cancer

Interventions
1. Schedule A: Combination chemotherapy, four 3 weekly cycles of mitomycin, ifosfamide and cisplatin (MIC). Followed by radiotherapy as decided by the radiotherapist. The total minimum dose should not be less than 40 Gy in fifteen fractions and the field size adequate to encompass the known extent of the tumour.

2. Schedule B: Radiotherapy as decided by the radiotherapist. The total minimum dose should not be less than 40 Gy in fifteen fractions and the field size adequate to encompass the known extent of the tumour.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mitomycin, ifosfamide and cisplatin

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1990

Completion date
01/01/1996

Eligibility

Key inclusion criteria
1. Age 75 years or under
2. Histologically or cytologically proven non-small cell lung cancer, ie adeno- squamous or large cell carcinoma
3. Clinically or radiologically evaluable disease 4. Inoperable, but clinically limited stage disease
5. WHO performance status of 0-2
6. No previous chemotherapy or radiotherapy
7. No metastatic disease, except ipsilateral stem cell factor (SCF) lymphadenopathy
8. Normal renal function
9. No other previous or concurrent malignancy, except cone biopsied carcinoma in-situ of the cervix and adequately treated basal cell carcinoma of the skin
10. No pleural effusion or symptomatic superior vena cava obstruction
11. No pre-existing severe impairment of lung function likely to prejudice the safe administration of the proposed radiotherapy
12. No indication that protocol treatment would exacerbate a serious pre-existing medical condition

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1990

Date of final enrolment
01/01/1996

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	interim analysis	01/04/1995		Yes	No
Results article	results	01/10/1999		Yes	No