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Mitomycin, ifosfamide and cisplatin in non-small cell lung cancer (NSCLC): a randomised trial of chemotherapy versus symptomatic treatment only in patients not suitable for radical radiotherapy

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 30/10/2019	**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
LU3002

Study information

Scientific Title
Mitomycin, ifosfamide and cisplatin in non-small cell lung cancer (NSCLC): a randomised trial of chemotherapy versus symptomatic treatment only in patients not suitable for radical radiotherapy

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 (non-small cell) cancer

Interventions
1. Schedule A: Combination chemotherapy, four, 3 weekly cycles of mitomycin, ifosfamide and cisplatin (MIC). Radiotherapy may be given to patients whose symptoms are not responding to the systemic therapy (in this case chemotherapy should be stopped), and to patients developing symptoms after chemotherapy has stopped. Short and simple radiotherapy schedules of one to ten fractions, not exceeding a total dose of 30 Gy should be given.

2. Schedule B: Palliative care only. Radiotherapy should be used where appropriate. Short and simple schedules of one to ten fractions, not exceeding a total dose of 30 Gy.

Intervention Type

Mixed

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1995

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. World Health Organisation (WHO) performance status of 0-2
6. No previous chemotherapy or radiotherapy
7. No cerebral metastases, spinal cord compression or symptomatic superior vena cava obstruction
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 indication that protocol treatment would exacerbate a serious pre-existing medical condition

Participant type(s)
Patient

Age group
Mixed

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
01/01/1995

Date of final enrolment
01/01/1996

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
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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

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	presumed results	01/10/1999	30/10/2019	Yes	No