ISRCTN56319613 https://doi.org/10.1186/ISRCTN56319613

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

Registration date
01/07/2001

Overall study status
Completed

Last Edited
01/02/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

ClinicalTrials.gov (NCT)
NCT00003240

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex

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
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
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

IPD sharing plan summary

Study outputs

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