

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
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/10/2019	Condition category Cancer	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(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. 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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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**

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

IPD sharing plan summary

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