

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

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/02/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## 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**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	01/10/1999		Yes	No
<a href="#">Other publications</a>	interim analysis	01/04/1995		Yes	No