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# A randomised study of Gemcitabine with Carboplatin versus Mitomycin, Vinblastine and Cisplatin (MVP) or Mitomycin C, Ifosfamide and Cisplatin (MIC) chemotherapy in inoperable advanced stage non-small cell lung cancer (NSCLC)

| | | |
|---|---|---|
| **Submission date**<br>12/09/2003 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>12/09/2003 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>05/10/2012 | **Condition category**<br>Cancer | [_] Individual participant data |

**Plain English summary of protocol**
http://cancerhelp.cancerresearchuk.org/trials/chemotherapy-in-nonsmall-cell-lung-cancer-gemcitabine-and-carboplatin-compared-to-mic

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N0063072220

# Study information

### Scientific Title

### Study objectives
The aim of the study is to compare the response rate, time to progression and the survival of patients randomised either to receive Gemcitabine with Carboplatin or MVP/MIC.

### 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
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Cancer: Non small cell lung cancer

### Interventions
Randomised, phase III, comparative trial.

### Intervention Type

Drug

### Phase
Phase III

### Drug/device/biological/vaccine name(s)
Gemcitabine with Carboplatin versus Mitomycin, Vinblastine and Cisplatin (MVP) or Mitomycin C, Ifosfamide and Cisplatin (MIC)

### Primary outcome measure
survival

### Secondary outcome measures
1. time to progression
2. response rates
3. evaluation of toxicity
4. disease-related symptoms
5. World Health Organization performance status
6. quality of life

### Overall study start date
01/04/1998

### Completion date
01/11/2001

## Eligibility

### Key inclusion criteria
1. NHS patients with pathologically confirmed NSCLC, stage IIIa, IIIb, or IV
2. ineligible for curative radical radiotherapy or surgery after discussion in a multidisciplinary team setting comprised of at least a chest physician, a surgeon, and an oncologist
3. no previous chemotherapy
4. age older than 18 years
5. life expectancy of at least 12 weeks
6. adequate bone marrow reserve (leukocyte count > 3 × 10^9/L, platelet count > 100 × 10^9/L, and hemoglobin > 100 g/dL)
7. creatinine clearance > 60 mL/minute
8. adequate birth-control measures

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex

Both

### Target number of participants
660 targeted, 372 recruited

### Key exclusion criteria
1. active infection
2. bony disease as the only measurable disease
3. prior radiotherapy to the sole site of assessable disease
4. inadequate renal or hepatic function
5. serious comorbidity
6. other malignancy (except in situ carcinoma of the cervix or adequately treated basal cell carcinoma of the skin)
7. peripheral neuropathy Grade > 2
8. significant neurologic or psychiatric disorder
9. symptomatic brain metastases

### Date of first enrolment
01/04/1998

### Date of final enrolment
01/11/2001

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Medical Oncology**
Manchester
United Kingdom
M20 4BX

## Sponsor information

### Organisation
Department of Health (UK)

### Sponsor details
Richmond House
79 Whitehall
London

United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.doh.gov.uk

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Christie Hospital NHS Trust (UK)

# 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 | results | 01/08/2003 | | Yes | No |