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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 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 05/10/2012	**Condition category** 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