

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/10/2012	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

survival

Key secondary outcome(s))

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

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 $> 3 \times 10^9/L$, platelet count $> 100 \times 10^9/L$, and hemoglobin > 100 g/dL)
7. creatinine clearance > 60 mL/minute
8. adequate birth-control measures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre**Medical Oncology**

Manchester

United Kingdom

M20 4BX

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Christie Hospital NHS Trust (UK)

Results and Publications

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				

[Results article](#)

01/08/2003

Yes

No