

A Phase III randomised comparison of Gemcitabine/Carboplatin with Mitomycin, Ifosfamide and Cisplatin in non-small cell lung cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2021	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/chemotherapy-in-nonsmall-cell-lung-cancer-gemcitabine-and-carboplatin-compared-to-mic>

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number

Study 11

Study information

Scientific Title

A Phase III randomised comparison of Gemcitabine/Carboplatin with Mitomycin, Ifosfamide and Cisplatin in non-small cell lung cancer

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. GC Arm: 3-weekly regimen. Gemcitabine 1200 mg/m² IV (Day 1 and 8) Carboplatin (AUC 5). Dose calculated according to the formula: Dose = Target area under curve x (creatinine clearance + 25) IV (Day 1)

2. MIC 3-Weekly regimen: Mitomycin 6 mg/m² IV (Day 1) Ifosfamide 3 g/m² IV (Day 1) Cisplatin 50 mg/m² IV (Day 1)

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Gemcitabine/Carboplatin with 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

31/08/2001

Eligibility

Key inclusion criteria

1. Histologically or cytologically proven non-small cell carcinoma of the lung
2. Stage IIIb or IV disease
3. Measurable or evaluable disease
4. Adequate renal function (Ethylene diamine tetraacetic acid [EDTA] Clearance >60 ml/min)
5. Age 18 or over
6. Adequate contraception in females of child-bearing potential
7. Written informed consent
8. No prior radiotherapy or chemotherapy
9. Not less than 8 weeks life expectancy
10. No history of prior malignancy (except non-melanomatous skin tumour or has been without evidence of disease for 3 years or more)
11. White cell count >3000/ml Platelet count >100,000/ml Haemoglobin >10.0 g.dL
12. No symptomatic brain metastases

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

422

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1995

Date of final enrolment

31/08/2001

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
London Lung Cancer Group (UK)

Funder(s)

Funder type
Research organisation

Funder Name
London Lung Cancer Group (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/01/2005		Yes	No
Plain English results		08/09/2009	29/10/2021	No	Yes