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

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

Plain English summary of protocol

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

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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

Drug/device/biological/vaccine name(s)

Gemcitabine/Carboplatin with Mitomycin, Ifosfamide and Cisplatin

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1995

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 Haemaglobin >10.0 g.dL
- 12. No symptomatic brain metastases

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Not provided at time of registration

Total final enrolment

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

England

United Kingdom

Study participating centre UKCCCR Register Co-ordinator

London United Kingdom NW1 2DA

Sponsor information

Organisation

London Lung Cancer Group (UK)

Sponsor details

-

London United Kingdom

none@provided.com

Sponsor type

Research organisation

Funder(s)

Funder type

Research organisation

Funder Name

London Lung Cancer Group (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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