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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

Registration date
19/08/2002

Overall study status
Completed

Last Edited
29/10/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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United Kingdom
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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

Phase III

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

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
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