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A Phase III Randomised comparison of Gemcitabine/Carboplatin with Cisplatin /Etoposide in Small Cell Lung Cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
Study 10

Study information

Scientific Title
A Phase III Randomised comparison of Gemcitabine/Carboplatin with Cisplatin/Etoposide in 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

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Lung (small cell) cancer

Interventions
1. GC Arm: 3-weekly regimen (6 cycles) Gemcitabine 1200 mg/m(2) IV (Day 1 and 8) Carboplatin (AUC 5) Dose in mg calculated according to the formula: Dose = Target area under curve x (creatinine clearance + 25) IV (Day1)

2. PE Arm: 3-weekly regime (6 cycles): Cisplatin 60 mg/m2 IV Day 1 Etoposide 120 mg/m2 IV (Day 1) and 100 mg bd po (days 2 and 3)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Cancer drugs

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/10/2001

Eligibility

Key inclusion criteria

1. Histologically or cytologically proven small cell anaplastic carcinoma of the lung
2. Extensive stage disease or limited stage but locally advanced or limited stage with poor prognostic factors
3. Measurable or evaluable disease
4. Adequate renal function for chemotherapy
5. Age 18 years or above
6. Adequate contraception for women of child bearing potential
7. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
241

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1996

Date of final enrolment
31/10/2001

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
NCRI CSG and London Lung Cancer Group (UK)

ROR
https://ror.org/02mp0vf47

Funder(s)

Funder type
Research organisation

Funder Name
NCRI CSG and 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	01/06/2001		Yes	No
Plain English results		08/09/2009	29/10/2021	No	Yes