

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/10/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

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 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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Lung (small cell) cancer

Interventions

1. GC Arm: 3-weekly regimen (6 cycles) Gemcitabine 1200 mg/m² 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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1996

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

NCRI CSG and London Lung Cancer Group (UK)

Sponsor details

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London

United Kingdom

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Sponsor type

Research organisation

ROR

<https://ror.org/02mp0vf47>

Funder(s)

Funder type

Research organisation

Funder Name

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