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A British Thoracic Oncology Group phase III trial of Gemcitabine plus Cisplatin at 80 mg/m^2 versus Gemcitabine plus Cisplatin at 50 mg/m^2 versus Gemcitabine plus Carboplatin area under the concentration-time curve (AUC) 6 in stage IIIB/IV non-small cell lung cancer (NSCLC)

Submission date 05/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 12/10/2020	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-chemotherapy-for-advanced-non-small-cell-lung-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00112710

Protocol serial number
LU 3005

Study information

Scientific Title
A British Thoracic Oncology Group phase III trial of Gemcitabine plus Cisplatin at 80 mg/m^2 versus Gemcitabine plus Cisplatin at 50 mg/m^2 versus Gemcitabine plus Carboplatin area under the concentration-time curve (AUC) 6 in stage IIIB/IV non-small cell lung cancer (NSCLC)

Acronym
BTOG2

Study objectives
To establish the optimal cisplatin dose and whether carboplatin can be effectively substituted for the cisplatin at this dose

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)
Treatment

Health condition(s) or problem(s) studied
Non-small cell lung cancer

Interventions
Chemotherapy - Gemcitabine plus Cisplatin at 80 mg/m^2 versus Gemcitabine plus Cisplatin at 50 mg/m^2 versus Gemcitabine plus Carboplatin AUC 6

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Gemcitabine, cisplatin, carboplatin

Primary outcome(s)

Length of survival

Key secondary outcome(s))
1. Symptom control and quality of life
2. Response to treatment
3. Dose intensity of chemotherapy
4. Ratio of cycles given as in-patient versus out-patient
5. Intensity, number and duration of toxic episodes (grade two to four)
6. Costs
7. Proteomic and genomic

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Histologically or cytologically confirmed NSCLC (excluding mixed SCLC/NSCLC)
2. Radiologically verified stage IIIB (unsuitable for radical radiotherapy) or stage IV disease
3. Presence of one or more clinically or radiological measurable lesions by Response Evaluation Criteria in Solid Tumors (RECIST) criteria
4. World Health Organisation (WHO) Performance status zero, one or two
5. Aged over 18 years
6. Life expectancy more than 12 weeks
7. Adequate haematological function and hepatobiliary function
8. Creatinine clearance: 60 ml/min or 70 ml/min (51Cr-EDTA)
9. Able to participate in the quality of life assessment
10. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1363

Key exclusion criteria
1. Prior chemotherapy or radiotherapy (prior surgical resection is allowed)
2. Evidence of severe or uncontrolled systemic diseases

3. Evidence of significant clinical disorder or laboratory finding
4. Concomitant or previous malignancy likely to interfere with protocol treatment or comparisons
5. Pre-existing neuropathy grade more than two
6. Clinically apparent metastatic disease to brain
7. Unresolved toxicity or incomplete recovery from previous surgery
8. Psychiatric disorder making informed consent impossible or preventing completion of treatment or follow-up
9. Previous investigational agent in the last 12 weeks
10. Male and female patients (of childbearing age) not using adequate contraception
11. Female patients who are pregnant or breast-feeding

Date of first enrolment
01/04/2005

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Wolverhampton Hospitals NHS Trust
Wolverhampton
United Kingdom
WV10 0QP

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No
Results article	results	01/09/2017	12/10/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes