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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

**Registration date**
09/09/2005

**Overall study status**
Completed

**Last Edited**
12/10/2020

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number
NCT00112710

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure
Length of survival

### Secondary outcome measures
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

### Overall study start date
01/04/2005

### 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

### Age group

Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
1350

### 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
England

United Kingdom

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

# Sponsor information

### Organisation
University of Birmingham

### Sponsor details
Research Support Group
Aston Webb Building, Room 117
Edgbaston
Birmingham
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United Kingdom
B15 2TT
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### Sponsor type
University/education

### Website
http://www.birmingham.ac.uk/index.aspx

### 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, CRUK

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
United Kingdom

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

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