

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

<b>Submission date</b> 05/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/10/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

### Contact name

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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<sup>2</sup> versus Gemcitabine plus Cisplatin at 50 mg/m<sup>2</sup> 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<sup>2</sup> versus Gemcitabine plus Cisplatin at 50 mg/m<sup>2</sup> 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?
<a href="#">Results article</a>	results	01/12/2011		Yes	No
<a href="#">Results article</a>	results	01/09/2017	12/10/2020	Yes	No
<a href="#">Plain English results</a>				No	Yes