

# A randomised study to assess whether the administration of amifostine with modified Ifosfamide, Carboplatin and Etoposide (ICE) chemotherapy attenuates the toxicity treatment in patients with good prognosis small cell lung cancer

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	
<b>Last Edited</b> 06/11/2012	<b>Condition category</b> Cancer	

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
DART

# Study information

## Scientific Title

## Study objectives

Added 07/08/09:

The aim of this trial is to determine whether the administration of amifostine before each cycle of modified ICE can attenuate the toxicity of the chemotherapy.

As of 07/08/09 this trial has been extensively updated. All updates can be found under the relevant field with the above update date. Please note that the start and end dates of this trial were changed from 01/08/2002 and 01/08/2003 respectively as these dates were automatically generated at the time of registration.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Multicentre randomised open label controlled parallel group trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Lung (small cell) cancer

## Interventions

Patients are randomised to one of two treatment groups:

1. Group A: Amifostine infusion followed immediately by modified chemotherapy with Ifosfamide, Carboplatin and Etoposide (ICE). Cycle repeated every 21 days for six cycles
2. Group B: Modified chemotherapy with ICE. Cycle repeated every 21 days for six cycles

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Amifostine, ifosfamide, carboplatin, etoposide

## Primary outcome(s)

Added 07/08/09:

Haematological toxicity; occurrence of WHO grade 3 or 4 neutropenia or thrombocytopenia during any course of chemotherapy

### **Key secondary outcome(s)**

Added 07/08/09:

1. Response rate
  2. Non-haematological toxicity
  3. Survival
  4. Hospitalisation
  5. Antibiotic usage
  6. Anti-emetic usage
  7. Transfusions
  8. Renal impairment
  9. Health Economic (HE) assessment
- Cost effectiveness

### **Completion date**

31/12/2000

## **Eligibility**

### **Key inclusion criteria**

1. Patients with histologically or cytologically proven non-small cell lung cancer
2. Patients with either:
  - 2.1. Limited disease with World Health Organisation (WHO) performance status zero to one
  - 2.2. Limited disease performance status two, normal sodium and alkaline phosphatase
  - 2.3. Extensive disease, performance status zero to one, normal sodium alkaline phosphatase, and no documented Central Nervous System (CNS) disease
3. Aged under 75 years
4. Systolic blood pressure of at least 90 mmHg
5. Adequate renal and hepatic function

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Prior cytotoxic therapy or radiotherapy
2. History of other malignant disease (except basal cell carcinoma or squamous cell cancer of the skin or in situ carcinoma of the cervix)

3. Symptomatic heart disease or other active infection or illness which would preclude chemotherapy

**Date of first enrolment**

01/11/1996

**Date of final enrolment**

31/12/2000

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

## **Sponsor information**

**Organisation**

Northern and Yorkshire Clinical Trials and Research Unit (UK)

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Northern and Yorkshire Clinical Trials and Research Unit (UK)

## **Results and Publications**

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?
<a href="#">Results article</a>	results	05/01/2001		Yes	No