

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

Submission date 19/08/2002	Recruitment status 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
Registration date 19/08/2002	Overall study status Completed	
Last Edited 06/11/2012	Condition category Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Added 07/08/09:

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

Secondary outcome measures

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

Overall study start date

01/11/1996

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

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration

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**

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

Northern and Yorkshire Clinical Trials and Research Unit (UK)

Sponsor details

17 Springfield Mount
Leeds
United Kingdom
LS2 9NG

Sponsor type

Research organisation

Website

http://www.leeds.ac.uk/medicine/nyctr/ctr_content.htm

Funder(s)

Funder type

Research organisation

Funder Name

Northern and Yorkshire Clinical Trials and Research Unit (UK)

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?
Results article	results	05/01/2001		Yes	No