ISRCTN91918581 https://doi.org/10.1186/ISRCTN91918581

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

Registration date
19/08/2002

Overall study status
Completed

Last Edited
06/11/2012

Condition category
Cancer

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

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 not 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:
Haemotological 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-haemological toxicity
3. Survival
4. Hospitalisation
5. Antibiotic usage
6. Anti-emetic usage
7. Transfusions
8. Renal impairment
9. Health Economonic (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/nyctru/ctru_contents.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