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A phase III randomised, double blind, placebo controlled trial of carboplatin/etoposide with or without thalidomide in small cell lung cancer

Submission date 02/07/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/07/2003	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-of-chemotherapy-with-or-without-thalidomide-in-small-cell-lung-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00061919

Secondary identifying numbers
Cancer Research UK Ref. C1438/A2932

Study information

Scientific Title
A phase III randomised, double blind, placebo controlled trial of carboplatin/etoposide with or without thalidomide in small cell lung cancer

Acronym
Study 12

Study objectives
Since tumour growth and metastasis are angiogenesis dependent, therapeutic strategies aimed at inhibiting angiogenesis are theoretically attractive. Thalidomide has anti-angiogenic and anti-cachexic effects which may complement the anti-tumour effect obtained from chemotherapy. Preliminary data from a recently completed phase II trial in SCLC appeared to show promising clinical activity when thalidomide was added to chemotherapy and as maintenance therapy. The combination was well tolerated without adding to the expected toxicities of the chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Small cell lung cancer

Interventions

Patients on both arms will receive carboplatin on day one and etoposide on day one, two and three on a three weekly regimen (six cycles).

All patients will be randomised to receive either thalidomide or placebo daily beginning on day one for up to 24 months.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Cisplatin and Etoposide (PE Chemotherapy) and thalidomide.

Primary outcome measure
To determine if survival is affected by the addition of thalidomide in patients with SCLC treated with carboplatin/ etoposide.

Secondary outcome measures
To determine the effects of thalidomide on: time to disease progression, toxicity, response rate, quality of life and, in selected centres, biological markers.

Overall study start date
01/04/2003

Completion date
07/11/2005

Eligibility

Key inclusion criteria
1. Histologically or cytologically confirmed small cell lung cancer
2. Limited or extensive stage disease
3. Have had no prior chemotherapy or radiotherapy
4. Have no symptomatic brain metastases thought to require immediate radiotherapy
5. No evidence of significant medical condition or laboratory finding which, in the opinion of the investigator, makes it undesirable for the patient to participate in the trial
6. Either sex, age over 18
7. Eastern Cooperative Oncology Group (ECOG) performance status zero to three
8. Estimated life expectancy of at least eight weeks
9. Renal function adequate for chemotherapy i.e. Ethylene Diamine Tetraacetic Acid (EDTA) clearance greater than 60 ml/min
10. Women of Child-Bearing Potential (WCBP) MUST have a negative serum or urine pregnancy test (minimal sensitivity 50 mIU/mL) performed by healthcare professional within 24 hours before starting study medication
11. WCBP must agree to practice complete abstinence from heterosexual intercourse or to use two methods of contraception (must include one highly effective barrier method [i.e. intrauterine device, hormonal birth control pills, injections or implants, tubal litigation, partners vasectomy) and one additional effective barrier method (i.e. latex or polyurethane condom,

diaphragm, cervical cap) while on study medication and for four weeks after the last dose of study medication
12. WCBP who are sexually active in a heterosexual relationship must agree to have pregnancy tests every four weeks while on study medication and four weeks after the last dose of study medication
13. Male patients (including those who have had a vasectomy) must use barrier contraception (latex or polyurethane condoms) when engaging in heterosexual activity with WCBP while on study medication and four weeks after the last dose of study medication
14. Pregnant or lactating women or WCBP not using adequate contraception are excluded.
15. All WCBP who have had unprotected sexual intercourse within two weeks prior to study entry should not start study until the beginning of her next period or a negative pregnancy test
16. No history of prior malignant tumour, unless patient has been without evidence of disease for at least three years or the tumour was a non-melanoma tumour or early cervical cancer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
372

Total final enrolment
724

Key exclusion criteria
1. Pregnant or lactating women or WCBP not using adequate contraception
2. Prior treatment with chemotherapy or radiotherapy
3. Evidence of significant medical condition or laboratory finding which, in the opinion of the investigator, makes it undesirable for the patient to participate in the trial
4. Prior history of thromboembolic event (including: Pulmonary Embolism [PE], Deep Vein Thrombus [DVT], Cerebro-Vascular Accident [CVA] / Transient Ischaemic Attack [TIA])
5. Symptomatic brain metastases thought to require immediate radiotherapy
6. History of prior malignant tumour, unless the patient has been without evidence of disease for at least three years or the tumour was a non-melanoma skin tumour or early cervical cancer

Date of first enrolment
01/04/2003

Date of final enrolment
07/11/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Middlesex/UCL Hospitals
London
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Sponsor information

Organisation
Sponsor not defined - Record supplied by London Lung Cancer Group

Sponsor details
N/A
London
United Kingdom
N/A
-
none@provided.com

Sponsor type
Not defined

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref. C1438/A2932)

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
Not provided at time of registration

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	05/08/2009		Yes	No
Plain English results		09/07/2010	29/10/2021	No	Yes