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A phase II/III randomised, double blind, placebo controlled trial of gemcitabine/carboplatin with or without thalidomide in advanced Non-Small Cell Lung Cancer (NSCLC)

Submission date
02/07/2003

Registration date
02/07/2003

Last Edited
29/10/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

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

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A phase II/III randomised, double blind, placebo controlled trial of gemcitabine/carboplatin with or without thalidomide in advanced Non-Small Cell Lung Cancer (NSCLC)

Acronym
LLCG Study 14

Study objectives
Primary objective:
To determine if survival is affected by the addition of thalidomide in patients with Non-Small Cell Lung Cancer (NSCLC) treated with gemcitabine/carboplatin.

Secondary objective:
To determine the effects of thalidomide on:
1. Time to disease progression
2. Toxicity
3. Response rate
4. Quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo 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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Non-small cell lung cancer

Interventions
Patients on the trial will receive up to 4 cycles of gemcitabine and carboplatin at 3 weekly intervals. Patients will be randomised to receive either thalidomide or placebo daily beginning on day 1 for up to 24 months.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Gemcitabine, carboplatin, thalidomide

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
07/09/2005

Eligibility

Key inclusion criteria
1. Histologically or cytologically confirmed NSCLC, stage IIIb or IV
2. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2 and estimated life expectancy of at least 8 weeks
3. Adequate renal function and bone marrow reserve
4. Women Of Childbearing Potential (WCBP) must agree to practice complete abstinence from heterosexual intercourse or to use TWO methods of contraception while on study medication, and have a negative serum or urine pregnancy test within the 24 hours before starting study medication. Those who are sexually active in a heterosexual relationship must agree to have pregnancy tests every 4 weeks while on study medication and 4 weeks after the last dose of study medication
5. Male patients (including those who have had a vasectomy) must use barrier contraception when engaging in heterosexual activity with WCBP while on study medication and 4 weeks after the last dose

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
514

Total final enrolment
722

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 3 years or the tumour was a non-melanoma skin tumour or early cervical cancer

Date of first enrolment
01/01/2003

Date of final enrolment
07/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Middlesex/UCL Hospitals
London
United Kingdom
W1T 3AA

Sponsor information

Organisation

Sponsor not defined - Record supplied by London Lung Cancer Group

Sponsor details
-
London
United Kingdom
-

Sponsor type
Not defined

Funder(s)

Funder type
Charity

Funder Name
London Lung Cancer Group (UK) (Charity no. 1074994) - LLCG study 14

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	01/11/2009		Yes	No
Plain English results		08/10/2010	29/10/2021	No	Yes