

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/07/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/10/2021	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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Additional identifiers

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Middlesex/UCL Hospitals

London

United Kingdom

W1T 3AA

Sponsor information

Organisation

Sponsor not defined - Record supplied by London Lung Cancer Group

Funder(s)

Funder type

Charity

Funder Name

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

Results and Publications

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