

# 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)

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

### Protocol serial number

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

## 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? |
|---------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>       | results | 01/11/2009   |            | Yes            | No              |
| <a href="#">Plain English results</a> |         | 08/10/2010   | 29/10/2021 | No             | Yes             |