

# A multicentre phase III randomised double-blind placebo-controlled trial of pravastatin added to first-line chemotherapy in patients with non-small cell lung cancer (LungStar 2 trial)

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<b>Registration date</b> 17/02/2006	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/04/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

N/A

# Study information

## Scientific Title

A multicentre phase III randomised double-blind placebo-controlled trial of pravastatin added to first-line chemotherapy in patients with non-small cell lung cancer (LungStar 2 trial)

## Acronym

Lungstar 2

## Study objectives

The aim of this study is to determine if survival is affected by the addition of pravastatin to docetaxel and cisplatin/carboplatin chemotherapy in patients with non-small cell lung cancer (NSCLC).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Double-blind placebo-controlled multicentre phase III study

## Primary study design

Interventional

## Study type(s)

Screening

## Health condition(s) or problem(s) studied

Stage 3B that is unsuitable for chemoradiation and stage 4 non-small cell lung cancer

## Interventions

Patients will receive chemotherapy with docetaxel and either carboplatin or cisplatin. They will be randomised to either pravastatin or placebo. Chemotherapy will last for four cycles unless there is evidence of progression or occurrence of unacceptable toxicities. Oral pravastatin or placebo will commence on day 1 of the first chemotherapy cycle.

Study entrants will be required to undergo all standard staging investigations. They will be required to provide a pre-chemotherapy full blood count as well as urea, creatinine and liver function tests before each cycle of chemotherapy. A staging computerised tomography (CT) scan will be performed mid-treatment (post cycle 2) and at the end of chemotherapy. A separate consent will be obtained for the collection of additional blood samples and tissue for translational research. A quality of life and toxicity questionnaire will be required at each visit.

## Intervention Type

Drug

## Phase

Phase III

**Drug/device/biological/vaccine name(s)**

Pravastatin, docetaxel, cisplatin, carboplatin

**Primary outcome(s)**

To determine if survival is affected by the addition of pravastatin to docetaxel and cisplatin /carboplatin chemotherapy in patients with non-small cell lung cancer.

**Key secondary outcome(s)**

1. Progression-free survival
2. Response rates and clinical benefit
3. Toxicity
4. Symptom control and quality of life

**Completion date**

01/06/2011

**Reason abandoned (if study stopped)**

Participant recruitment issue

**Eligibility****Key inclusion criteria**

1. Histological or cytological-confirmed NSCLC
2. Stage IV disease or stage IIIB disease that is unsuitable for radio-chemotherapy
3. Presence of one or more measurable lesions (by Response Evaluation Criteria in Solid Tumors [RECIST] criteria)
4. Estimated life expectancy of at least 12 weeks
5. Performance status 0, 1 or 2
6. Aged 18 or over
7. Patients must be able to give informed consent
8. Adequate haematological function (absolute neutrophil count [ANC] greater than  $1.5 \times 10^9$  /l, platelets greater than  $100 \times 10^9$  /l, and haemoglobin greater than 9 g/dl)
9. Adequate renal function: ethylenediaminetetraacetic acid (EDTA) based glomerular filtration rate of greater than 55 ml/min or a 24-hour creatinine clearance of greater than 60 ml/min
10. Adequate hepatobiliary function: serum bilirubin less than 1.5 times the upper limit of normal (ULN) and serum aspartate aminotransferase (AST) and/or alanine transaminase (ALT) less than 2.5 x ULN in patients without liver involvement or less than 5.0 x ULN in patients with liver metastases
11. Patient compliance and geographic proximity allowing for adequate follow-up
12. Female patients potentially able to bear children should use an approved contraceptive method (intrauterine device [IUD], birth control pills or barrier device) during and for three months after the study. All male patients should take adequate contraceptive precautions during and up to two months after the study
13. Written informed consent prior to admission to this study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Presence of central nervous system metastases
2. Prior chemotherapy or radiotherapy for this disease
3. Protocol chemotherapy should start after randomisation (except for example when a patient needs to start chemotherapy urgently, randomisation may occur at a maximum of one working day after day 1 of cycle 1 but consent to the trial must always be obtained prior to starting chemotherapy)
4. Creatinine kinase greater than or equal to 5 x ULN
5. Patients treated with statins (e.g. simvastatin, pravastatin, atorvastatin) within one year prior to randomisation
6. Patients treated with fibrates (e.g. bezofibrate, gemfibrozil, fenofibrate) within four weeks prior to randomisation
7. Patients on cyclosporine
8. Hypersensitivity to docetaxel, carboplatin, cisplatin or pravastatin or any of their excipients
9. 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
10. Evidence of uncontrolled infection
11. Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study
12. A 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
13. Pregnancy and lactation; effective contraception is mandatory for all patients of reproductive potential if sexually active whilst in the study. Contraception should continue for one year post completion of all chemotherapy or radiotherapy and a further 28 days after cessation of pravastatin/placebo

**Date of first enrolment**

01/06/2006

**Date of final enrolment**

01/06/2011

**Locations****Countries of recruitment**

United Kingdom

England

Ireland

**Study participating centre**  
Department of Medical Oncology  
London  
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## Sponsor information

**Organisation**  
Imperial College London

**ROR**  
<https://ror.org/041kmwe10>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Sanofi-Aventis

**Funder Name**  
Clinical Trials Advisory and Awards Committee

## Results and Publications

**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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes