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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)

Submission date
07/02/2006

Recruitment status
Stopped

Registration date
17/02/2006

Overall study status
Stopped

Last Edited
13/04/2017

Condition category
Cancer

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 x 10^9 /l, platelets greater than 100 x 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