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

Submission date
07/04/2006

Recruitment status
No longer recruiting

Registration date
08/05/2006

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-for-small-cell-lung-cancer-looking-at-chemotherapy-with-or-without-pravastatin

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00433498

Clinical Trials Information System (CTIS)
2005-005821-71

Protocol serial number
BRD/05/129

Study information

Scientific Title
A multicentre, phase III, randomised, double-blind, placebo-controlled trial of pravastatin added to first-line chemotherapy in patients with small cell lung cancer

Acronym
LungStar

Study objectives
To see if the addition of pravastatin to standard combination chemotherapy (cisplatin and etoposide or carboplatin and etoposide) improves response rates, time to disease progression, and survival in patients with Small Cell Lung Cancer (SCLC).

On 15/02/2011 the following changes were made to the trial record:
1. The anticipated end date was changed from 30/04/2010 to 31/10/2011.
2. The target number of participants was changed from 1300 to 860.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentre Research Ethics Committee for Scotland, 19/04/2006, ref: 06/MRE10/28

Primary study design
Interventional

Study design
Multicentre phase III randomised double-blind placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Small cell lung cancer

Interventions
All patients receive standard chemotherapy: Cisplatin/Etoposide or Carboplatin/Etoposide. They are then randomised prior to or within one working day of starting chemotherapy to:

1. Pravastatin daily for two years
2. Placebo daily for two years

Assessments with each cycle of chemotherapy then, follow up post chemotherapy, two monthly to one year from randomisation then three monthly thereafter.

Intervention Type

Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Pravastatin, cisplatin, carboplatin, etoposide

Primary outcome(s)
To determine in patients with SCLC if survival is affected by the addition of pravastatin to either cisplatin/etoposide or carboplatin/etoposide

Key secondary outcome(s)
To compare the treatments in terms of:
1. Progression-free survival
2. Local progression-free survival (local control)
3. Response rates
4. Toxicity

Completion date
31/10/2011

Eligibility

Key inclusion criteria
1. Histologically or cytologically confirmed SCLC
2. Limited or extensive disease
3. Performance status Eastern Cooperative Oncology Group (ECOG) zero to three
4. Life expectancy more than 8 weeks
5. Age 18 or over
6. Willing and able to give informed consent
7. Patient considered able to tolerate chemotherapy
8. Adequate renal function - defined by glomerular filtration rate (GFR) more than 50 ml/min if measured by EthyleneDiamineTetraacetic Acid (EDTA) or GFR more than 40 ml/min if measured by the Cockcroft and Gault (C & G) formula. Cisplatin and etoposide dose should be modified according to renal function as per dose modification schedule.
9. Adequate bone marrow reserve - Absolute Neutrophil Count (ANC) more than 1.5 x 10^9 /l, Haemoglobin (Hb) more than 10.0 g/dl and platelet count more than 100 x 10^9 /l
10. Liver function tests less than three times Upper Limit of Normal (ULN)
11. Creatine Kinase less than or equal to five times ULN

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Prior chemotherapy for this disease (protocol chemotherapy should start after randomisation except for where a patient needs to start chemotherapy urgently, randomisation may occur a maximum of one working day after day one of cycle one)
2. Prior radiotherapy for this disease (except for prior radiotherapy to distant metastases i.e. not within the thorax or thoracic or cervical spine is acceptable)
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. Patients with a family history of hypercholesterolaemia
5. 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
6. Patients treated with fibrates e.g. bezofibrate, gemfibrozil, fenofibrate within four weeks prior to randomisation
7. Patients on cyclosporin
8. Patients with symptomatic brain metastases, which require immediate radiotherapy
9. 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 or placebo
10. Treatment with any statin within previous 12 months

Date of first enrolment
01/06/2006

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Medical Oncology
London
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Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C1312/A5335)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/05/2017		Yes	No
Basic results				No	No
Plain English results			25/10/2022	No	Yes