

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

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|--|---|---|
| Submission date 07/04/2006 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 08/05/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 25/10/2022 | Condition category Cancer | <input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2005-005821-71

IRAS number

ClinicalTrials.gov number

NCT00433498

Secondary identifying numbers

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

Study design

Multicentre phase III randomised double-blind placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

To compare the treatments in terms of:

1. Progression-free survival
2. Local progression-free survival (local control)
3. Response rates
4. Toxicity

Overall study start date

01/06/2006

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 1.5×10^9 /l, Haemoglobin (Hb) more than 10.0 g/dl and platelet count more than 100×10^9 /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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

860

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**

England

United Kingdom

Study participating centre
Department of Medical Oncology
London
United Kingdom
W6 8RF

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
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England
United Kingdom
WC1E 6BT

Sponsor type
University/education

Website
<http://www.ucl.ac.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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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? |
|---------------------------------------|---------|--------------|------------|----------------|-----------------|
| Basic results | results | 10/05/2017 | | No | No |
| Results article | | | | Yes | No |
| Plain English results | | | 25/10/2022 | No | Yes |