ISRCTN14095893 https://doi.org/10.1186/ISRCTN14095893

# Addition of Ipilumimab to Carboplatin and Etoposide chemotherapy for the first line treatment of extensive small cell lung cancer

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| **Submission date**<br>06/05/2011 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>06/05/2011 | **Overall study status**<br>Completed | |
| **Last Edited**<br>24/03/2022 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-treating-small-cell-lung-cancer-ipilimumab-chemotherapy-ice

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**
2010-021863-34

**ClinicalTrials.gov (NCT)**
NCT01331525

**Protocol serial number**
9618

# Study information

## Scientific Title
A phase II trial of the addition of Ipilumimab to Carboplatin and Etoposide chemotherapy for the first line treatment of extensive small cell lung cancer

## Acronym
ICE Trial

## Study objectives
Primary Objective:
To establish the progression free survival at 1 year in patients with extensive stage small cell lung cancer treated with ipilimumab, carboplatin and etoposide.

Secondary Objectives:
To assess the response to and toxicity of the combination of ipilimumab with carboplatin and etoposide chemotherapy.

Immunological Objectives:
1. To examine whether ipilimumab stimulates a humoral immune response to onco-neuronal self-antigens
The results from the above measurement of antibodies against onco-neuronal antigens will be used to focus the cellular biomarker analysis and identify targets to assess cellular responses
2. To measure the effect of ipilimumab on CD8+ T-cells directed against onco-neuronal antigens, presumed to be responsible for the desired cytotoxic activity against cancer cells
3. To evaluate the immune response to non-neuronal antigens in the presence of ipilimumab

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Southampton & South West Hampshire REC Committee A, First MREC approval date 11/01/2011, 10/H0502/95

## Study design
Non-randomised; Interventional; Design type: Treatment

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Lung Cancer; Disease: Lung (small cell)

## Interventions
Carboplatin, Combination chemo for 6 cycles; Etoposide, Combination chemotherapy for 6 cycles; Ipilimumab, to be ngiven during cycles 3 - 6 and then as maintenance therapy every 12 weeks; Follow Up Length: 12 month(s); Study Entry : Registration only

### Intervention Type
Drug

### Phase
Phase II

### Drug/device/biological/vaccine name(s)
Ipilumimab, carboplatin, etoposide

### Primary outcome(s)
Progression free survival; Timepoint(s): from consent to patient disease progression

### Key secondary outcome(s))
1 year overall survival; Timepoint(s): survival one year from consent

### Completion date
29/05/2014

## Eligibility

### Key inclusion criteria
1. Willing and able to give written informed consent
2. Histological or cytological diagnosis of small cell lung cancer
3. Adequate baseline laboratory tests
4. No active or chronic infection with human immunodeficiency virus (HIV), hepatitis B, or hepatitis C.
5. Performance status Eastern Cooperative Oncology Group (ECOG) 0 or 1
6. Men and women, 18 years of age or more. ; Lower Age Limit 18 no age limit or unit specified

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Limited stage small cell lung cancer appropriate for radical treatment with chemoradiation
2. Symptomatic central nervous system (CNS) metastases
3. A history of prior malignant tumour, unless the patient has been without evidence of disease for at least 5 years, with the exception of adequately treated basal or squamous cell skin cancer,

superficial bladder cancer or carcinoma in situ of the cervix
4. Clinically significant autoimmune disease
5. Any underlying medical, neurological or psychiatric condition, which in the opinion of the investigator will make the administration of ipilimumab hazardous or obscure the interpretation of adverse effects (AEs).
6. Administration of any live vaccine for prevention of infectious diseases (for up to 1 month before or after any dose of ipilimumab)
7. Previous chemotherapy for small cell lung cancer
8. A history of prior treatment with immunostimulatory antibodies ipilimumab, prior CD137 agonist or CTLA 4 inhibitor or agonist
9. Concomitant therapy with any of the following: interleukin 2, interferon, or other non-study immunotherapy regimens; immunosuppressive agents; other investigation therapies; or chronic use of systemic corticosteroids
10. Women of childbearing potential (WOCBP), as defined in the protocol and who:
10.1. Are unwilling or unable to use an acceptable method of contraception to avoid pregnancy for the duration of their participation in the study and for at least 8 weeks after cessation of study drug
10.2. Have a positive pregnancy test at baseline
10.3. Are pregnant or breastfeeding

### Date of first enrolment
30/06/2011

### Date of final enrolment
29/05/2014

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
### Clinical Trials Unit
Southampton
United Kingdom
SO16 6YD

## Sponsor information

### Organisation
Southampton University Hospitals NHS Trust (UK)

### ROR
https://ror.org/0485axj58

# Funder(s)

**Funder type**
Industry

**Funder Name**
Bristol Myers Squibb Pharmaceuticals Ltd (UK)

**Funder Name**
Cancer Research UK (CRUK) (UK)

**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 | 01/09/2016 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Plain English results | | | 24/03/2022 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |