

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

Submission date 06/05/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/03/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

Ms Debbie Hamid

Contact details

Clinical Trials Unit, MP 131, Tremona Road

Southampton

United Kingdom

SO16 6YD

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d.hamid@soton.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT01331525

Clinical Trials Information System (CTIS)

2010-021863-34

Protocol serial number

9618

Study information

Scientific Title

A phase II trial of the addition of Ipilimumab 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 given 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