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Addition of Ipilumimab 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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/05/2011	**Overall study status** Completed	
Last Edited 24/03/2022	**Condition category** Cancer	

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

Study website
http://www.ctu.soton.ac.uk/trial.aspx?trialid=30

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-021863-34

IRAS number

ClinicalTrials.gov number
NCT01331525

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Progression free survival; Timepoint(s): from consent to patient disease progression

Secondary outcome measures
1 year overall survival; Timepoint(s): survival one year from consent

Overall study start date
01/05/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40; Description: 40 patients to be recruited from 5 sites across the UK

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
England

United Kingdom

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

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Tremona Road
Southampton
England
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Sponsor type
Hospital/treatment centre

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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

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?
Results article	results	01/09/2016		Yes	No
Plain English results			24/03/2022	No	Yes
HRA research summary			28/06/2023	No	No