




Trial Information Summary - STIMULI

STIMULI - Phase II trial to assess the overall survival benefit for patients with the use of Nivolumab and Ipilimumab in limited-stage small cell lung cancer (SCLC) after chemo-radiotherapy

Lung disease	Medicine	Outcome	Age: Over 18	Phase: Two	Status: Recruiting
			18+	II	
ALTG: 16/012		ANZCTR: ACTRN12618000918224			
The information contained in this document is intended for discussion with your health professional to help determine your potential eligibility.					

It is hoped that the findings from this trial will provide information on whether adding Nivolumab and Ipilimumab after standard chemotherapy / radiotherapy for patients with limited stage Small Cell Lung Cancer will help to stop the cancer coming back and how severe side effects are for standard chemotherapy/radiotherapy alone when compared to adding in Nivolumab and Ipilimumab (immunotherapy).

Inclusions – At Enrolment

- Adults, aged 18 years and older, with histologically or cytologically confirmed Small Cell Lung Cancer (SCLC);
- Untreated (with the exception of 1 cycle of chemotherapy given prior to enrolment) limited stage disease (LD) as defined by stage I-IIIb based on 7th TNM classification M0 – proven by;
- Whole body FDG-PET CT including a contrast CT of thorax and upper abdomen (incl. liver, kidney and adrenals)
- **OR** contrast-enhanced CT of thorax and upper abdomen (incl. liver, kidney and adrenals) and bone scan
- **AND** Brain MRI (or contrast enhanced CT of the brain) within 28 days before start of chemotherapy;
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1;
- Adequate haematological renal, hepatic and lung function;
- Pulmonary function FEV1 of 1.0L or greater than 40% predicted value and DLCO greater than 40% predicted value

Exclusions

- Patients with mixed Small Cell Lung Cancer and Non-Small Cell histologic features;
- Patients with pleural or pericardial effusions proven to be malignant;
- Documented history of severe autoimmune or immune mediated symptomatic disease that required prolonged (more than 2 months) systemic immunosuppressive treatment (steroids) such as ulcerative colitis, Crohn's disease, rheumatoid arthritis, systemic progressive sclerosis (scleroderma), systemic lupus erythematosus or autoimmune vasculitis (eg Wegener's granulomatosis);
- Patients with autoimmune paraneoplastic syndrome requiring concurrent immunosuppressive treatment are excluded;
- Interstitial Lung Disease or Pulmonary Fibrosis;
- Women who are pregnant or in the period of lactation;
- Patients with any concurrent anticancer systemic therapy (except chemotherapy cycle 1)
- HIV, Hepatitis B or Hepatitis C infection
- Patients who have had in the past 5 years any previous concomitant malignancy EXCEPT adequately treated basal or squamous cell carcinoma of the skin, insitu carcinoma of the cervix or bladder, insitu ductal carcinoma of the breast;
- Previous radiotherapy to the thorax (prior to inclusion)
- Planned mean lung dose greater than 20 Gy or V20 greater than 35%

This is a summary document of the inclusion and exclusion criteria of the study.
Please contact your oncologist or GP to discuss the full details of this trial.



NHMRC Clinical Trial Coordinator
stimuli@ctc.usyd.edu.au

ALTG Program Manager
altg@lungfoundation.com.au

Participating sites

State	Site
NSW	Royal North Shore Hospital – St Leonards
	Westmead Hospital Westmead
	St Vincent's Hospital (Darlinghurst)
	The Chris O'Brien Lifehouse - Camperdown
	Coffs Harbour Base Hospital – Coffs Harbour
	Gosford Hospital - Gosford
	The Tweed Hospital – Tweed Heads
	Port Macquarie Base Hospital – Port Macquarie
	Riverina Cancer Care Centre – Wagga Wagga
	Border Medical Oncology – Albury
Vic	Bendigo Hospital - Bendigo
	Epworth Richmond – Richmond
	Austin Health – Austin Hospital - Heidelberg
	Peninsula Oncology Centre – Frankston
QLD	Royal Brisbane & Women's Hospital - Herston
	Princess Alexandra Hospital – Woolloongabba
	The Townsville Hospital – Douglas
	Icon Cancer Care
	Gold Coast University Hospital – Southport
SA	Flinders Medical Centre – Bedford Park
Tas	Royal Hobart Hospital - Hobart