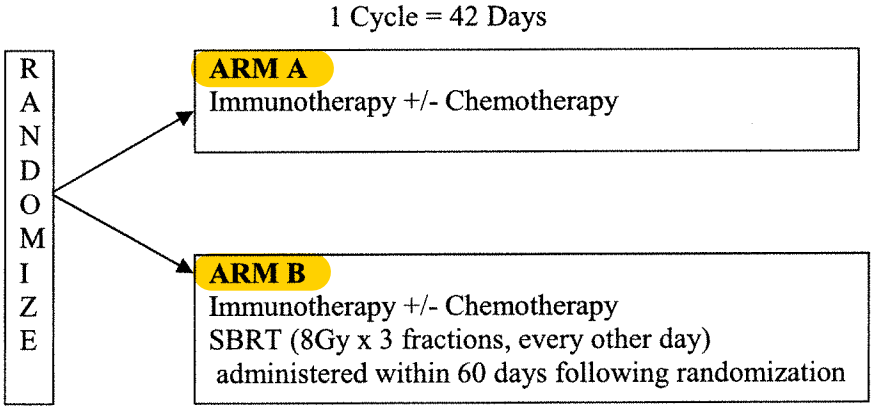
A RANDOMIZED PHASE II/III TRIAL OF MODERN IMMUNOTHERAPY BASED SYSTEMIC THERAPY WITH OR WITHOUT SBRT FOR PD-L1-NEGATIVE, ADVANCED NON-SMALL CELL LUNG CANCER

Eligibility Criteria	**Required Initial Laboratory Values**	
Histologic or cytologic documented NSCLC Stage IV or Stage IIIB-C if not a candidate for chemo-RT	ANC	$\geq 1500/mm^3$
PD-L1 TPS <1%	Platelet count	$\geq 100,000/mm^3$
EGFR, ALK and ROS1 negative (non-squam only)	Calc create Clear	≥ 45 ml/min
Measurable disease	Total Bili	≤ 1.5 x ULN
Age ≥ 18 years	AST/ALT	≤ 2.5 x ULN
ECOG PS 0-2		
No prior treatment per Section 3.2.5		
No comorbid conditions per Section 3.2.6		
Non-pregnant and non-nursing		
No currently active second malignancy		
No hypersensitivity to immunotherapy		
No live vaccine within 30 days		

Schema



Treatment will continue until disease progression and no longer benefiting clinically, or unacceptable adverse event. Treatment may continue beyond disease progression per iRECIST guidelines. That is, treatment may continue beyond assessment of progressive disease (PD) provided the patient is clinically stable and felt to be continuing to benefit from therapy. A patient may be deemed clinically stable provided that no worsening of performance status has occurred, there have been no clinically relevant increases in disease-related symptoms such as pain or dyspnea that are thought to be associated with disease progression, and there has been no requirement for intensified management of disease-related symptoms, including increased analgesia, radiotherapy, or other palliative care. Repeat imaging should be obtained within 4-8 weeks if feasible, and no later than 3 months. If the subsequent scan shows additional new lesions or increase in new lesion size (sum of measurements ≥ 5 mm), treatment should be discontinued.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.