ImmunoSABR (Academic)

Combination of SABR and L19-IL2 in Patients With Stage IV Lung Cancer (ImmunoSABR). This is the trial summary as assessed on clinicaltrials.gov on 09/07/2020.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT02735850?term=L19-IL2&cond=Lung+Cancer&draw=2&rank=1

Trial Design:

This will be a phase II trial testing if the combination of SBRT and L19-IL2 improves the progression free survival in patients with limited metastatic non-small cell lung cancer (NSCLC). Treatment will be divided in two cohorts: patients eligible for ablative stereotactic body radiotherapy to all metastatic sites (treatment with curative intent) and patients not eligible for stereotactic body radiotherapy to all sites (life prolongation).

Arm	Intervention
Experimental Ablative cohort	Ablative SBRT to all (max 3) sites followed by L19-IL2
Comparator Ablative cohort	Ablative RT to all (max 3) sites

Arm	Intervention
Experimental Non-ablative cohort	SBRT 1 site, L19-IL2 and then standard of care
Comparator Non-ablative cohort	Standard of care

Inclusion criteria:

- Histological confirmed limited metastatic NSCLC patients. Two cohorts of patients are allowed:
  - Synchronous oligometastatic eligible for ablative stereotactic body radiotherapy to all sites. These patients will have a maximum of 3 metastatic lesions (excluding the brain) eligible for ablative treatment using SABR

  - Other oligometastatic patients with up to 10 metastatic lesions, not eligible for ablative stereotactic body radiotherapy, that have controlled disease (i.e. no progressive disease according to RECIST 1.1) following primary chemotherapy with a platinum doublet, with at least one measurable lesion that is not subjected to stereotactic body radiotherapy (SABR)
- Radiological images documenting this lesion should be no older than 28 days before study enrolment
- Age of 18 y or older
- Prior treatments are allowed but must be discontinued for at least 4 weeks before enrolment
- All radiology studies must be performed within 28 days prior to registration

- WHO performance status 0-2
- Adequate bone marrow: Normal white blood cell count and formula, normal platelet count, no anemia requiring blood transfusion or erythropoietin
- Adequate hepatic function: total bilirubin ≤ 1.5 x upper limit of normal (ULN) for the institution; ALT, AST, and alkaline phosphatase ≤ 2.5 x ULN for the institution or <= 5 in case of liver metastasis)
- Adequate renal function: creatinine clearance at least 60 ml/min
- The patient is capable of complying with study procedures
- Life expectancy of at least 12 weeks
- Men and women with reproductive potential must be willing to practice acceptable methods of birth control during the study and for up to 12 weeks after the last dose of study medication
- Signed and dated written informed consent

Exclusion criteria:

- NSCLC with activating ALK/EGFR of ROS mutations
- SABR required to brain metastasis
- Previous chemotherapy other than a platinum doublet
- Patients with progressive disease following initial chemotherapy
- Previous chemotherapy for more than 25 weeks
- Previous radiotherapy to an area that would be re-treated by SABR
- Other active malignancy or malignancy within the last 2 years (with exception of localized skin basal/squamous cell carcinoma, bladder in situ carcinoma)
- History of allergy to intravenously administered proteins/peptides/antibodies
- HIV infection, active infection, or active hepatitis
- Chronic systemic use of corticosteroids used in the management of cancer or non-cancer-related illness
- Acute or sub-acute coronary syndromes within the last year, acute inflammatory heart disease, heart insufficiency or irreversible cardiac arrhythmias
- Impaired cardiac function defined as left ventricular ejection fraction (LVEF) < 50 % (or below the study site's lower limit of normal) as measured by MUGA or ECHO. (LVEF measurements dating back up to 8 weeks will be acceptable in the absence of intercurrent use of potentially cardiotoxic treatment or cardiac medical history)
- Uncontrolled hypertensive disease
- History or evidence of active autoimmune disease
- Severe diabetic retinopathy (neoangiogenesis targeted by L19 outside the tumor)
- Major trauma, including surgery, within 4 weeks prior to entering the study (neoangiogenesis targeted by L19 outside the tumor)
- Any underlying medical or psychiatric condition which in the opinion of the investigator will make administration of study drug hazardous or hinder the interpretation of study results (e.g., AE)
- Unstable or serious concurrent uncontrolled medical conditions
- Pregnancy or breast-feeding