A Randomized Double Blind Phase II Trial of Restorative Microbiota Therapy (RMT) or Placebo in Combination with Durvalumab (MEDI4736) and Tremelimumab With Chemotherapy in Treatment Naive Advanced or Metastatic Adenocarcinoma Non-Small Cell Lung Cancer

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- confirmed adenocarcinoma of the lung that is stage IIIB/C or stage IV that can't be surgically removed - prior chemotherapy or immunotherapy as adjuvant therapy for lung cancer is permitted as long as it has been more than 6 months from last dose

•people who have treated brain metastasis are eligible as long as they have stable symptoms, are more than 2 weeks from completion of therapy, and do not require more than 10mg of daily prednisone or equivalent - restricted in strenuous physical activity but can walk and carry out work of a light or sedentary nature, e.g., light house work, office work - weigh at least 30 kg (66 lbs.) - contact study staff for additional requirements

Exclusion Criteria:

- women who are pregnant or breast feeding - unable to swallow medications - additional medical and mental health diagnosis (study staff will review)

Conditions & Interventions

Conditions:
Cancer, Respiratory System
Keywords:
Clinics and Surgery Center (CSC), Adenocarcinoma of Lung, Lung Cancer

More Information

Description: This is a randomized, active-controlled, parallel-group, double-blind Phase II trial, of oral restorative microbiota therapy (RMT) or placebo combined with intravenous (IV) durvalumab (MEDI4736) plus tremelimumab and chemotherapy in patients with treatment naïve advanced or metastatic adenocarcinoma non-small cell lung cancer (NSCLC). The primary objectives include: -To evaluate the efficacy of restorative microbiota therapy (RMT) in combination with durvalumab and tremelimumab plus chemotherapy compared with placebo in combination with durvalumab and tremelimumab plus chemotherapy using PFS per RECIST 1.1 as assessed by the investigator -To evaluate the safety and feasibility of restorative microbiota therapy (RMT) in combination with durvalumab and tremelimumab plus chemotherapy in patients with untreated advanced or metastatic adenocarcinoma non-small cell lung cancer (NSCLC)
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