

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

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy 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: The investigational therapy in this study is referred to as Restorative Microbiota Therapy (RMT). It is prepared by extracting healthy bacteria from the stool of healthy human donors and making it into capsules taken by mouth. The donor stool samples are rigorously tested for harmful bacteria and viruses before processing. There is scientific evidence to suggest that RMT might make immunotherapy more effective. The primary goal of the study is to test if RMT makes durvalumab + tremelimumab treatment with chemotherapy more effective to control lung cancer.

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Phase: Phase 2

IRB

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