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Participating sites:

- UF Health Cancer Center/Preston A. Wells Jr. Center for Brain Tumor Therapy at UF (enrolling)

Sponsors

- Monteris Medical is paying for this research study

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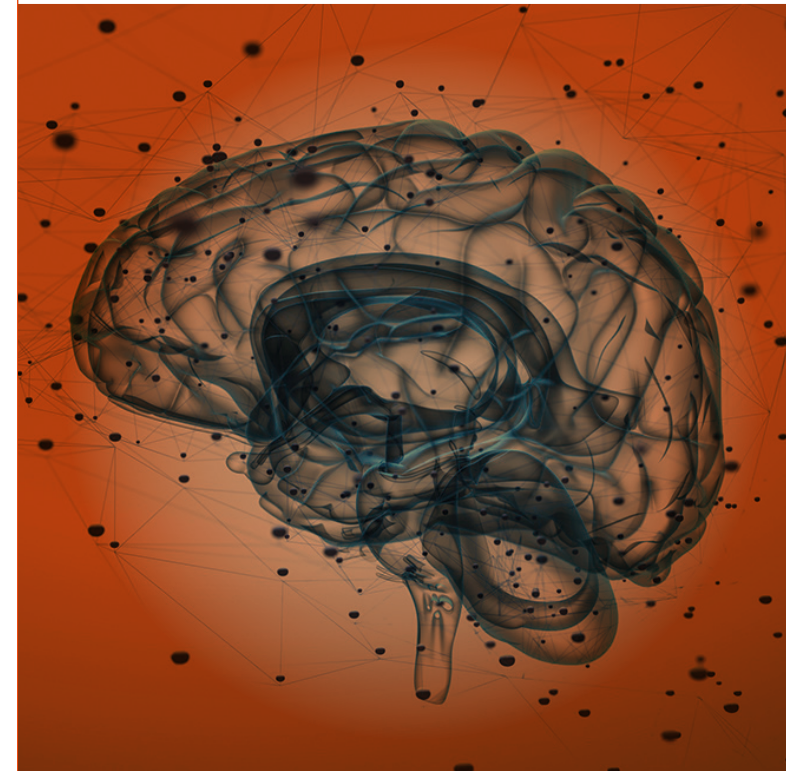
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PRESTON A. WELLS JR.
CENTER FOR BRAIN TUMOR THERAPY
UNIVERSITY OF FLORIDA

TORCH CLINICAL TRIAL

*Recurrent Brain Metastasis Immune Effects
 and RespOnse to Laser Interstitial
 ThermostHerapy (LITT) and Pembrolizumab
 in Combination (TORCH)*





Purpose

The purpose of this research study is to determine if laser interstitial thermotherapy (LITT) plus pembrolizumab is effective in treatment of brain metastases that recur after stereotactic radiosurgery.

This is a pilot study seeking 15 patients for enrollment at the University of Florida.

All study patients will receive both LITT and pembrolizumab.

TORCH Overview

- ▶ Patients with brain metastases from a primary cancer approved by the FDA for treatment with an immune-checkpoint inhibitor
- ▶ Patients must have had stereotactic radiosurgery on at least 1 lesion previously and demonstrate tumor growth
- ▶ Patients will undergo biopsy and LITT, then begin pembrolizumab infusions every 3 weeks, continuing for up to 2 years

Eligible patients

- ▶ Primary Melanoma, Non-Small Cell Lung Cancer, Small Cell Lung Cancer, Head and Neck Squamous Cell Cancer, Classical Hodgkin Lymphoma, Primary Mediastinal Large B-Cell Lymphoma, Urothelial Carcinoma, Microsatellite Instability-High Cancer, Gastric Cancer, Esophageal Cancer, Cervical Cancer, Hepatocellular Carcinoma, Merkel Cell Carcinoma, or Renal Cell Carcinoma
- ▶ Imaging demonstrating metastases (1-3 lesions) where at least one lesion has had prior stereotactic radiosurgery and demonstrates tumor growth
- ▶ 18 years or older
- ▶ No active viral or autoimmune disease

Study activities for patients

- ▶ Screening blood tests, physical exam and MRI
- ▶ Biopsy and LITT
- ▶ Pembrolizumab given every 3 weeks by infusion
- ▶ Periodic MRIs and routine clinical appointments for monitoring purposes are required
- ▶ Research blood and tumor tissue collected for immune monitoring