

Doctor's Note — Clinical Trial Summary

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TRIAL

Transarterial Chemoembolization for the Treatment of Uveal Melanoma With Liver Metastases

NCT ID: NCT04728633 Phase: PHASE2 Sponsor: Thomas Jefferson University Status: Active Not Recruiting

SUMMARY

This phase II trial studies the effect of transarterial chemoembolization in treating patients with uveal melanoma that has spread to the liver (liver metastases). Transarterial chemoembolization involves the injection of a blocking agent (gelatin sponge, ethiodized oil) and a chemotherapy agent (carmustine) directly into the artery in the liver to treat liver cancers. Chemotherapy drugs, such as carmustine, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. transarterial chemoembolization with carmustine in combination with ethiodized oil and gelatin sponge may help cause the tumors in the liver to shrink or disappear.

KEY ELIGIBILITY CRITERIA

- * Histologically confirmed metastatic uveal melanoma in the liver
- * Tumor burden $\leq 75\%$. Patients must have at least one tumor measuring ≥ 10 mm in longest diameter by magnetic resonance imaging (MRI) or triphasic computed tomography (CT) (if MRI is not available or contraindicated)
- * No prior transarterial catheter-directed therapies. Prior hepatic tumor ablation, hepatic radiation or liver resection will be permitted as long as growing measurable liver tumors exists. Prior systemic treatments are allowed as long as there are no outstanding toxicities greater than grade 1
- * Willingness and ability to give informed consent
- * Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
- * Serum creatinine ≤ 2.0 mg/dl
- * Bilirubin ≤ 2.0 mg/ml. Exceptions will be made for patients with diagnosed Gilbert's Syndrome. In this instance, a bilirubin level ≤ 3.0 mg/ml will be allowed for this patients with this syndrome
- * Albumin ≥ 3.0 g/dl
- * No ascites
- * Granulocyte count $\geq 1500/m^3$

Total sites: 1 | 0 currently recruiting