ROWAN: An Open-Label, Prospective, Multi-Center, Randomized Clinical Trial To Evaluate The Efficacy and Safety Of TheraSphereTM followed by Durvalumab (Imfinzi®) With Tremelimumab, Versus TheraSphereTM Alone For Hepatocellular Carcinoma (HCC).

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- not a candidate for liver resection, thermal ablation, or transplantation - not able to do strenuous activity but walking and able to carry out work of a light or sedentary nature, e.g., light house work, office work - body weight >30 kg (66 lbs) and BMI ≥18 kg/m2 - must use adequate contraception - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- metastasis of the cancer outside the liver - history or organ or bone marrow transplant - active or prior documented autoimmune or inflammatory disorders - women who are pregnant or breastfeeding and who do not want to stop breastfeeding - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Drug: Durvalumab (Imfinzi) immunotherapy, Device: TheraSphere Y-90 glass microsphere therapy, Drug: Tremelimumab immunotherapy
Conditions:
Cancer
Keywords:
HCC, Hepatocellular cancer, Liver Cancer

More Information

Description: We are studying a treatment for people who have hepatocellular carcinoma that will be treated with TheraSphere™, a device that delivers radiation directly to the tumor. The study will determine if adding immunotherapy medications after TheraSphere™ treatment is safe and can improve results.
Study Contact: Deb Mailand - mailand@umn.edu
Principal Investigator: Siobhan Flanagan
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