**Protocol Title:** Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma

**Target Population:**
- Adult Primary Hepatocellular Carcinoma
- Advanced and Recurrent Primary Liver Cancer

**Summary:** To determine if Stereotactic Body Radiation Therapy (SBRT) improves overall survival in Hepatocellular Carcinoma (HCC) patients treated with Sorafenib (Sorafenib Tosylate).

**Key Inclusion Criteria:**
- Patients must have a diagnosis of HCC by at least 1 criterion listed below within 360 Days prior to study entry:
  - Pathologically (histologically or cytologically) proven diagnosis of HCC, (biopsies are recommended, and are to be submitted for research evaluation if patients consent)
  - At least 1 solid Liver Lesion or Vascular Tumor Thrombosis (involving Portal Vein, Inferior Vena Cava, and / or Hepatic Vein) > 1 cm with arterial enhancement and delayed washout on multi-phasic CT or MRI in the setting of Cirrhosis or Chronic Hepatitis B or C without Cirrhosis.
  - For patients whose CURRENT disease is vascular only: Enhancing Vascular Thrombosis (involving Portal Vein, IVC, and / or Hepatic Vein) demonstrating early arterial enhancement and delayed washout on multi-phasic CT or MRI in a patient with known HCC (diagnosed previously < 720 Days) using the above criteria.
- Measureable Hepatic Disease and / or presence of Vascular Tumor Thrombosis (involving Portal Vein, IVC and / or Hepatic Vein) which may not be measureable on Liver CT or MRI, within 28 Days of registration.
- Albumin ≥ 2.8 g/dL.
- Unsuitable for resection or transplant or Radiofrequency Ablation (RFA)
- Unsuitable for or refractory to Transarterial Hepatic Chemo-Embolization (TACE) or drug eluting beads.

**Key Exclusion Criteria:**
- Prior Sorafenib use > 60 Days.
  - Note: Prior Chemotherapy for HCC or a different cancer is allowable.
- Prior Radiotherapy to the region of the Liver that would result in overlap of radiation therapy fields.
- Prior Selective Internal Radiotherapy / Hepatic Arterial Yttrium Therapy, at any time.
- Any 1 Hepatocellular Carcinoma > 15 cm.
- Total maximal sum of Hepatocellular Carcinomas or a single conglomerate HCC > 20 cm.
- More than 5 discrete Intrahepatic Parenchymal Foci of HCC.
- Direct tumor extension into the Stomach, Duodenum, Small Bowel, or Large Bowel.
- Measureable Common or Main Branch Biliary Duct involvement with HCC.
- Extrahepatic Metastases or Malignant Nodes > 3.0 cm.
  - Note: Benign non-enhancing Periportal Lymphadenopathy is not unusual in the presence of Hepatitis and is permitted, even if the sum of enlarged nodes is > 2.0 cm
- Use of regular Phenytoin, Carbamazepine, Hypericum Perforatum (also known as St. John's Wort) or Rifampin.
- Prior liver transplant.

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**For additional information:** [https://clinicaltrials.gov/ct2/show/NCT01730937](https://clinicaltrials.gov/ct2/show/NCT01730937)