# ULTRA-HFIB-Redo: Ultrasound-based Renal Sympathetic Denervation Vs Control in Redo Ablation Patients

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

**Inclusion Criteria:**

* Age ≥ 18; * Planned for a redo AF ablation procedure (paroxysmal or persistent); (prior to randomization, a technically successful AF ablation procedure, defined as successful pulmonary vein isolation, if needed, as well as bidirectional block of any attempted anatomic lesion sets such as cavotricuspid isthmus line, roofline, mitral line and superior vena cava isolation, must have been completed). Note: the clinical recurrences must primarily be atrial fibrillation, and not atrial flutter/tachycardia (that is, a prospective patient may have a AFL/AT recurrences, but AF must be the dominant recurrent rhythm.) * History of hypertension and either: * Documented history of SBP≥160 or DBP≥100, or; * Receiving ≥1 antihypertensive medication; * Willingness to adhere to study restrictions and comply with all post-procedural follow-up requirements

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**Exclusion Criteria:**

* Long-standing persistent AF (\>12 months); \>3 prior atrial fibrillation ablations (lifetime); AF ablation within 3 months of enrollment; extensive scar in left atrium. * Individual with valvular AF or AF due to a reversible cause * Prior treatment with other devices for hypertension including but not limited to ROX Coupler, Mobius stent, and/or the CVRx barostimulator device. * NYHA class IV congestive heart failure; * Individual has renal artery anatomy that is ineligible for treatment (as determined by renal angiography); * Main renal artery diameter \<3mm or \>8.0 mm * Main renal treatable artery length \< 20 mm (length may include proximal branches) * Presence of renal artery stenosis of any origin ≥30% * Calcification in renal arteries * Prior renal denervation procedure * Presence of abnormal kidney tumors * Renal artery aneurysm * Pre-existing renal stent or history of renal artery angioplasty * Pre-existing aortic stent or history of aortic aneurysm * Fibromuscular disease of the renal arteries * Iliac/femoral artery stenosis precluding insertion of the Paradise Catheter * Individual has an estimated glomerular filtration rate (eGFR) of less than 40mL/min/1.73m2, using the MDRD calculation; * Inability to undergo AF catheter ablation (e.g., presence of a left atrial thrombus, contraindication to all anticoagulation) * Individual with known allergy to contrast medium not amendable to treatment. * Life expectancy \<1 year for any medical condition * Individual has experienced a myocardial infarction, unstable angina, cerebrovascular accident, or heart failure admission within 3 months of the baseline visit. * Documented history of chronic active inflammatory bowel disorders such as Crohn's disease or ulcerative colitis. * Female participants who are pregnant or nursing. * Individual has known secondary hypertension. * Individual has a single functioning kidney (either congenitally or iatrogenically). * Individual has a known, unresolved history of drug use or alcohol dependency, lacks the ability to comprehend or follow instructions, or would be unlikely or unable to comply with study follow-up requirements. * Patients concurrently enrolled in any other investigational drug or device trial that would interfere with the conduction of this protocol.

## Conditions & Interventions

**Interventions:**
DEVICE: Renal Denervation, DEVICE: Catheter Ablation
**Conditions:**
Paroxysmal Atrial Fibrillation, Persistent Atrial Fibrillation

## More Information

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**Principal Investigator:**
**Phase:** NA
**IRB**
**Number:**
**System ID:** NCT05988411

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