PROTOCOL SUMMARY

Title:	CORAL: Cardiovascular Outcomes in Renal Atherosclerotic Lesions
Design:	A prospective, multi-center, unblinded, two-arm, randomized trial
Purpose:	This study is designed to test the hypothesis that medical therapy with stenting of significant renal artery stenoses in patients with systolic hypertension reduces the incidence of adverse cardiovascular and renal events compared with medical therapy alone.
Brief Description:	This study will enroll patients with a history of systolic hypertension, who have documented renal artery stenosis. Patients will be randomized via several pathways to either medical therapy or medical therapy with renal artery stenting and be closely monitored for blood pressure control and management of other risk factors. A subgroup of 400 patients will undergo renal artery Duplex ultrasound at baseline, 1 year and study termination. All patients will have quality of life measures performed, and cost effectiveness data will be collected for analysis.
Enrollment:	1080 patients evaluable Up to 400 roll-in patients (a minimum of 1 patient per site)
Clinical Sites:	Up to 100 study sites in the United States and 100 sites outside the United States
Time Course:	Initial enrollment: Q1 2005 Last anticipated enrollment: Q1 2009 Last follow-up contact: Q3 2010
Patient Population:	Patients over 18 years old with documented history of hypertension on ≥ 2 antihypertensive medications and/or renal dysfunction defined as Stage 3 or greater CKD (estimated GFR < 60 mL per minute per 1.73 m^2 calculated by the modified MDRD formula) and ≥ 1 renal artery stenosis $\geq 60\%$ and <100%
Primary Endpoint:	Event-free survival from cardiovascular and renal adverse events defined as a composite of cardiovascular or renal death, stroke, MI, hospitalization for CHF, progressive renal insufficiency, or need for permanent renal replacement therapy.

Secondary Endpoints:

1. Rate of all cause mortality
2. Subgroup interaction in critical subgroups:
   - Men vs. women
   - African Americans vs. non-African Americans
   - Diabetes vs. non-Diabetes mellitus
   - Global vs. Partial renal ischemia
3. Longitudinal renal function
4. Systolic blood pressure response
5. Durability of renal artery patency after stenting
6. Evaluation of renal resistive index: a measure of preservation of microvascular renal artery function
7. Correlation between stenosis severity and kidney function
8. Quality of life
9. Cost effectiveness

Primary Analytical Subset: Intent-to-treat sample

Secondary Analytical Subset: Per protocol (successful procedure) sample

Study Chairman:	Lance D. Dworkin, MD Director, Division of Renal Diseases Professor of Medicine Brown University, Rhode Island Hospital Providence, RI
Co-Chairman:	William L. Henrich, MD, M.A.C.P. Dean, School of Medicine Vice President for Medical Affairs University of Texas HSC San Antonio, Texas
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