



Prairie

EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

CORAL

- Trial Sponsor:** National Heart, Lung, and Blood Institute (NHLBI)
- Principal Investigator:** Jeffrey Goldstein, MD
- Trial Name:** Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL)
- Purpose:** This study will compare medical therapy plus stenting of hemodynamically significant renal artery stenoses versus medical therapy alone in patients with systolic hypertension and renal artery stenosis.

Details:

Atherosclerotic renal artery stenosis is a common problem for which there is no clear consensus on diagnosis or therapy. There likely exists a progression in which renal ischemia leads to neuroendocrine activation, hypertension, and renal insufficiency resulting in acceleration of atherosclerosis, further renal dysfunction, and development of left ventricular hypertrophy. These events in turn lead to adverse clinical events.

Renal artery stenosis is one of the two major known causes of hypertension and occurs in 1-5% of hypertensive patients. In patients with accelerated hypertension, the prevalence of renal artery stenosis is much higher, ranging from 10-40%. Renal artery stenosis, when occurring bilaterally, or in a solitary kidney, is a significant cause for end-stage renal disease, accounting for several percent of patients with end-stage renal disease. Clinically, atherosclerotic renal artery stenosis is a major problem primarily in older patients, and is often seen in long-standing hypertensives whose blood pressure becomes very difficult to control. Of major significance is the progressive nature of atherosclerotic renal artery stenosis, progressing at the rate of about 10% per year (45-60% progression rate in 4-7 year follow-ups). Over this time period, 10-15% of patients develop total renal artery occlusion. If the renal artery stenosis is greater than 75% when detected, 40% of patients develop total occlusion. Due to the progressive nature of atherosclerotic lesions, the decline in renal function in some individuals, and difficult-to-control hypertension, the medical community has sought to detect those patients in whom intervention would be beneficial. This has been extremely difficult to achieve and tests to date have not been uniformly predictive, including peripheral vein plasma renin activity, renal vein renin activity, captopril-stimulated nuclear medicine renal scans, etc.

Since approximately 50% of patients with unilateral renal artery stenosis of significant degree (definitions vary) benefit from surgical intervention, enthusiasm has continued with the advent of renal artery



Prairie

EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

angioplasty. The entire field is moving very quickly. However, there are neither current data nor prospective studies indicating the benefit of renal artery angioplasty plus stents. Studies over the last decade have shown that balloon angioplasty alone is associated with a high rate of recurrence in patients with atherosclerotic renal artery stenosis. In the present climate, there is great enthusiasm to perform angioplasty plus stent placement in atherosclerotic renal artery stenosis, without supporting data for efficacy compared to medical management alone. Angioplasty and stent placement in the renal arteries had been the domain of interventional radiologists, but recently, interventional cardiologists are also performing these procedures. The questions as to who will benefit from intervention and which intervention to use have not been answered. Renal artery angioplasty and stent placement subjects the patient to procedural risks, as well as increased cost, when compared to aggressive antihypertensive medication and risk factor medication and therapy.

<u>Phase:</u>	Phase III
<u>Study Type:</u>	Interventional
<u>Study Design:</u>	Treatment, Randomized
<u>Expected Enrollment:</u>	1,080
<u>Study Start:</u>	April 2004
<u>Expected Completion:</u>	March 2010

Primary Outcome Measures:

- cardiovascular or renal death
- myocardial infarction
- hospitalization for congestive heart failure
- stroke
- doubling of serum creatinine levels
- and need for renal replacement therapy



Prairie

EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

Eligibility:

Ages Eligible for Study: 18 years and above

Genders Eligible for Study: Both

Inclusion Criteria:

- Documented history of hypertension on two or more anti-hypertensive medications OR renal dysfunction, defined as Stage 3 or greater chronic kidney disease (CKD) based on the new National Kidney Foundation (NKF) classifications (estimated glomerular filtration rate [GFR] less than 60 mL per minute per 1.73 m², calculated by the modified Modification of Diet in Renal Disease [MDRD] formula)
- One or more severe renal artery stenoses by any of the following pathways:
 - Angiographic: greater than or equal to 60% and less than 100% by renal angiogram OR
 - Duplex: systolic velocity of greater than 300 cm/sec OR
 - Core lab approved magnetic resonance angiogram (MRA) (refer to the protocol for specific criteria)