

RENAAL STUDY

Backgrounder

Definition

- RENAAL stands for **R**eduction of **E**ndpoints in **N**on-insulin dependent diabetes mellitus with the **A**ngiotensin II **A**ntagonist **L**osartan.

Objective

- The RENAAL study was undertaken to find out if COZAAR® (losartan potassium)—a medication indicated for the treatment of hypertension (high blood pressure)—has an effect of slowing down the progression of renal disease in people with type 2 diabetes (non-insulin dependent diabetes mellitus), suffering from hypertension or not, in other words, independent of its effect on hypertension. **The question addressed by this study is: does taking losartan reduce the progression of kidney disease in patients with type 2 diabetes and established kidney disease?**

Design

- RENAAL is a multicentred, international, double-blind, placebo-controlled, randomized trial with a total of 1,513 patients enrolled.
- Male and female patients between the ages of 31 to 70 diagnosed with type 2 diabetes and established kidney disease with or without hypertension were recruited for the study.
- Recruitment began in June, 1996 and the study ended in February, 2001.
- Patients were randomly assigned to one of two groups, one taking COZAAR® (50 mg or 100 mg once daily), and the other taking a placebo. Those with hypertension also continued their usual antihypertensive therapy that could include diuretics, vasodilators, calcium channel blockers and/or beta blockers, but could **not** include ACE (angiotensin-converting enzyme) inhibitors and other AIIAs (angiotensin II antagonists). Maintaining adequate and equal blood pressure control (target: 140/90 mmHg) in both groups was essential.

Endpoints (results assessment)

Primary endpoint

- To determine the impact of losartan on the progression of kidney disease as assessed by the length of time it takes for doubling serum creatinine (the level of creatinine in the blood is an indirect measure of how well the kidneys are functioning), to reach end-stage renal disease, or death.

Secondary endpoints

To assess the effect of losartan compared to placebo on:

- Decreasing sickness and death caused by cardiovascular (heart and circulation-related) disease;
- Slowing down the progression of renal disease;
- Reducing protein in the urine;
- Safety and tolerability.

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