CSP 465-FS
The Veterans Administration Diabetes Trial Follow-Up Study (VADT-FS)
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Background/Rationale:
CSP #465, "Glycemic Control and Complications in Diabetes Mellitus Type 2," also known as the Veterans Administration Diabetes Trial (VADT) was a randomized unblinded clinical trial comparing the effect of tight glycemic control to standard glycemic control on cardiovascular morbidity and mortality. The study was conducted at 20 VA medical centers. One thousand seven hundred and ninety two patients were randomized over the 2 ½ year accrual period and then followed for an additional 5 years. Follow-up averaged between 5 and 7 ½ years depending upon when the patient was enrolled in the study. High blood pressure and elevated cholesterol were aggressively treated in patients in both treatment arms. Although active clinical follow-up of the sample ended on May 31, 2008 there is reason to believe that many of the macrovascular and microvascular complications potentially prevented by the 5-8 years of good glycemic control achieved in the VADT will occur years after completion of the VADT experimental protocol.

Objectives:
The VADT Follow-up study is a longitudinal observational follow-up study of the VADT with the following objectives: 1) to determine the long term effects of intensive glycemic control in type 2 diabetes on major cardiovascular complications (primary outcome), and 2) to determine the long term effects of intensive glycemic control in type 2 diabetes on four secondary outcomes: a) cardiovascular mortality, b) major microvascular complications, c) health-related quality of life, and d) total mortality.

Methods:
The follow up study will consist of centralized computer database searches and an annual survey to assesses quality of life and self-reported events pertinent to the CSP #465 endpoints. All VADT study subjects active at the end of the experimental study are being asked to participate in the VADT-FS. Every 12 months (starting in approximately June 2009), a standardized self-administered instrument will be mailed to each participant to obtain information on: 1. self-reported health status, 2. occurrence of study end-points, and 3. outpatient visits, hospitalizations and procedures. In addition, electronic data from the VA's central data repositories (such as the Medical SAS datasets at Austin, which contain inpatient and outpatient data, and the DSS lab and pharmacy National Data Extracts) will be extracted every 6 months.

Findings/results:
Start-up activities are still underway and there are no findings to report.

Impact:
Observational follow-up of the VADT population will also represent the only large, clinically-detailed US cohort study of type 2 diabetes in the modern treatment era. Type 2 diabetes is a complex, multi-system disease in which complications often unfold over many years, and yet few longitudinal studies of diabetes in the US have ever assessed cardiovascular and other end-stage outcomes over more than a 5-10 year period.