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A New Long-term Study of Diabetes Drug Efficacy

VA San Diego Healthcare System (VASDHS) is looking for volunteers to take part in a study to compare the long-term benefits and risks of four widely used diabetes drugs in combination with metformin, the most common first-line medication for treating [type 2 diabetes](#). The study began recruitment in June and the project is called the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) Study.

If metformin is not enough to help manage type 2 diabetes, a person's doctor may add one of several other drugs to lower glucose (blood sugar). But while short-term studies have shown the efficacy of different drugs when used with metformin, there have been no long-term studies of which combination works best and has fewer side effects.

"GRADE is a novel and exciting study which has the potential of changing the future of therapy and management of type 2 diabetes," said Robert Henry, MD, local principal investigator, chief of Endocrinology, Metabolism & Diabetes at VASDHS and professor of Medicine at the University of California, San Diego School of Medicine. The study will compare drug effects on glucose levels, adverse effects, diabetes complications and quality of life over an average of nearly five years.

GRADE aims to enroll about 5,000 patients. Investigators at VA San Diego Healthcare System and 36 other study sites are seeking people diagnosed with type 2 diabetes within the last five years. Veterans and non-Veterans are eligible to participate in the study if they meet the study criteria. They may be on metformin, but not on any other diabetes medication. During the study, all participants will take metformin, along with a second medication randomly assigned from among four classes of medications, all approved for use with metformin by the U.S. Food and Drug Administration.

Three of the classes of medications increase insulin levels. They are: sulfonylurea, which increases insulin levels directly; DPP-4 inhibitor, which indirectly increases insulin levels by increasing the effect of a naturally occurring intestinal hormone; and GLP-1 agonist, which increases the amount of insulin released in response to nutrients. The fourth type of medication is a long-acting insulin.

Participants will have their diabetes medications managed free of charge through the study, including at least four medical visits per year, but will receive other health care through their own providers.

What differentiates GRADE from previous studies is that it will perform a head-to-head comprehensive comparison of the most commonly used drugs over a long period of time," said David M. Nathan, M.D., of Massachusetts General Hospital, Boston. Nathan and John Lachin, Sc.D., of The George Washington University, Washington, D.C., are co-principal investigators.

“In addition to determining which medications control blood glucose levels most effectively over time, we hope to examine individual factors that are associated with better or worse response to the different medications,” Nathan said. “This should provide understanding of how to personalize the treatment of diabetes.”

GRADE (ClinicalTrials.gov number: NCT01794143) is supported under NIH grant U01DK098246. Additional support in the form of donation of supplies comes from the [National Diabetes Education Program](#), Sanofi-Aventis, Bristol-Myers Squibb, Novo Nordisk, Merck, BD Medical and Roche Diagnostics.

Learn more about the study at <https://grade.bsc.gwu.edu>.

VA San Diego Healthcare System GRADE study contacts:

Catherine DeLue	(858) 552-8585 ext. 6740
Erick Castro	(858) 552-8585 ext. 6449