Duke Medicine News & Communications
(919) 684-4148
http://dukemednews.org

Contact: Rachel Harrison
Phone: (919) 419-5069
E-mail: rachel.harrison@duke.edu

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Duke Medicine researchers to examine if vitamin D prevents diabetes

NIH-funded research tests much-touted vitamin in people with prediabetes

Duke Medicine is looking for volunteers to take part in the first definitive, large-scale clinical trial to investigate if a vitamin D supplement helps prevent or delay type 2 diabetes in adults who have prediabetes, who are at high risk for type 2. Funded by the National Institutes of Health, the study is taking place at about 20 study sites across the United States.

The multiyear Vitamin D and Type 2 Diabetes (D2d) study will include about 2,500 people. Its goal is to learn if vitamin D – specifically D3 (cholecalciferol) – will prevent or delay type 2 diabetes in adults aged 30 or older with prediabetes. People with prediabetes have blood glucose levels that are higher than normal but not high enough to be called diabetes.

"While there has been a lot of interest in taking vitamin D supplements and measuring vitamin D levels in recent years, many of the purported health benefits of vitamin D, including effects on diabetes risk, have not yet been proven," said Ranee Chatterjee Montgomery, M.D., MPH, assistant professor of medicine. "We are excited to be a part of this multi-center trial which will help determine if vitamin D supplements can be used as an adjunct treatment, in addition to healthy lifestyle, to help prevent diabetes."

D2d is the first study to directly examine if a daily dose of 4,000 International Units (IUs) of vitamin D – greater than a typical adult intake of 600-800 IUs a day, but within limits deemed appropriate for clinical research by the Institute of Medicine – helps keep people with prediabetes from getting type 2 diabetes. Based on observations from earlier studies, researchers speculate that vitamin D could reduce the diabetes risk by 25 percent. The study will also examine if sex, age or race affect the potential of vitamin D to reduce diabetes risk.

"An estimated 79 million Americans have prediabetes, and nearly 26 million more have diabetes," said Griffin P. Rodgers, M.D., director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of NIH. "With D2d, we seek evidence for an affordable and accessible way to help prevent or delay type 2 diabetes."

Researchers are recruiting volunteers to take part in D2d. Half of the participants will receive vitamin D. The other half will receive a placebo – a pill that has no drug effect. Participants will have check-ups for the study twice a year, and will receive regular health care through their own health care providers.

The study will be double-blinded, so neither participants nor the study's clinical staff will know who is receiving vitamin D and who is receiving placebo. The study will continue until enough people have developed type 2 diabetes to be able to make a scientifically valid comparison between diabetes development in the two groups, likely about four years.

D2d builds on previous NIH-funded studies of methods to delay or prevent type 2 diabetes, including the Diabetes Prevention Program, which showed that, separately, lifestyle changes to lose a modest amount of weight and the drug metformin are both effective in slowing development of type 2 diabetes in people with prediabetes. However, additional safe and effective preventative strategies are needed to stem the increasing numbers of people developing type 2 diabetes.

D2d (ClinicalTrials.gov number NCT01942694) is supported under NIH grant U01DK098245. The NIDDK is the primary sponsor of the trial, with additional support from the NIH Office of Dietary Supplements and the American Diabetes Association. Support in the form of educational materials is provided by the National Diabetes Education Program.

If you are interested in joining D2d as a study participant in the Durham area, please contact Duke Medicine at 919-668-7863 or D2dstudy@dm.duke.edu. Learn more about the study at www.D2dstudy.org.

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